

**HEALTH SERVICES AND DEVELOPMENT AGENCY MEETING
JUNE 25, 2014
APPLICATION SUMMARY**

NAME OF PROJECT: Dyersburg Regional Medical Center

PROJECT NUMBER: CN1403-007

ADDRESS: 400 Tickle Street
Dyersburg (Dyer County), TN 38024

LEGAL OWNER: Dyersburg Hospital Corporation
c/o Community Health Systems Professional
Services Corp.
4000 Meridian Blvd.
Franklin, (Williamson County), TN 37067

OPERATING ENTITY: Not Applicable

CONTACT PERSON: Jerry W. Taylor, Esquire
(615) 782-2228

DATE FILED: March 14, 2014

PROJECT COST: \$367,763.00

FINANCING: Cash Reserves

PURPOSE OF REVIEW: Expansion of Existing Cardiac Catheterization
Services to include Interventional Cardiac
Catheterization

DESCRIPTION:

Dyersburg Regional Medical Center (DRMC) is seeking approval for the expansion of its cardiac catheterization services, currently limited to diagnostic procedures, to include interventional (therapeutic) cardiac catheterization services located at 400 Tickle Street, Dyersburg (Dyer County), TN 38024.

SPECIFIC CRITERIA AND STANDARDS REVIEW:

Cardiac Catheterization Services

Applicants proposing to provide any type of cardiac catheterization services must meet the following minimum standards:

- I Compliance with Standards: The Division of Health Planning is working with stakeholders to develop a framework for greater accountability to these Standards and Criteria. Applicants should indicate whether they intend to collaborate with the Division and other stakeholders on this matter.

The applicant intends to collaborate with the Division of Health Planning and other stakeholders.

It appears that this criterion is met.

2. Facility Accreditation: If the applicant is not required by law to be licensed by the Department of Health, the applicant should provide documentation that the facility is fully accredited or will pursue accreditation by the Joint Commission or another appropriate accrediting authority recognized by the Centers for Medicare and Medicaid Services (CMS).

The applicant has provided documentation that the applicant is licensed by the Department of Health and certified by the Joint Commission.

It appears that this criterion is met.

3. Emergency Transfer Plan: Applicants for cardiac catheterization services located in a facility without open heart surgery capability should provide a formalized written protocol for immediate and efficient transfer of patients to a nearby open heart surgical facility (within 60 minutes) that is reviewed/tested on a regular (quarterly) basis.

The applicant has transfer agreement protocols with the Regional Hospital of Jackson, Methodist University Hospital-Memphis, St. Francis-Memphis and Vanderbilt University-Nashville. A table of

ground/air nautical distance and travel time are listed in a table in Supplement One.

It appears that this criterion is met.

4. Quality Control and Monitoring: Applicants should document a plan to monitor the quality of its cardiac catheterization program, including, but not limited to, program outcomes and efficiency. In addition, the applicant should agree to cooperate with quality enhancement efforts sponsored or endorsed by the State of Tennessee, which may be developed per Policy Recommendation 2.

The applicant has provided a plan to monitor quality and states the quality enhancement efforts by the State of Tennessee will be followed.

It appears that this criterion is met.

5. Data Requirements: Applicants should agree to provide the Department of Health and/or the Health Services and Development Agency with all reasonably requested information and statistical data related to the operation and provision of services and to report that data in the time and format requested. As a standard of practice, existing data reporting streams will be relied upon and adapted over time to collect all needed information.

The applicant agrees to provide all relevant requested data.

It appears that this criterion is met.

6. Clinical and Physical Environment Guidelines: Applicants should agree to document ongoing compliance with the latest clinical guidelines of the American College of Cardiology/Society for Cardiac Angiography and Interventions Clinical Expert Consensus Document on Cardiac Catheterization Laboratory Standards (ACC Guidelines).

Where providers are not in compliance, they should maintain appropriate documentation stating the reasons for noncompliance and the steps the provider is taking to ensure quality. These guidelines include, but are not limited to,

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physical facility requirements, staffing, training, quality assurance, patient safety, screening patients for appropriate settings, and linkages with supporting emergency services.

The applicant has agreed to comply with the latest clinical and physical environmental guideline of the American College of Cardiology/Society for Cardiac Angiography and Interventions and physical environment guidelines.

It appears that this criterion is met.

7. Staffing Recruitment and Retention: The applicant should generally describe how it intends to maintain an adequate staff to operate the proposed service, including, but not limited to, any plans to partner with an existing provider for training and staff sharing.

Experienced staff from other Community Health Systems (CHS) hospitals will provide cardiac catheterization services training and staff support. DRMC plans to recruit additional experienced personnel to complement existing staff.

It appears that this criterion is met.

8. Definition of Need for New Services: A need likely exists for new or additional cardiac catheterization services in a proposed service area if the average current utilization for all existing and approved providers is equal to or greater than 70% of capacity (i.e., 70% of 2000 cases) for the proposed service area.

Dyersburg Regional Medical Center and Baptist-Union City are the only providers of diagnostic catheterization services in the six county Tennessee service area. The Tennessee Department of Health calculated the percent of existing services to capacity in the service area was 21.9% of the 2000 case per lab threshold for the period 2010-2012.

It appears that this criterion is not met.

9. Proposed Service Areas with No Existing Service: In proposed service areas where no existing cardiac catheterization service exists, the applicant must show the data and methodology used to estimate the need and demand for the service. Projected need and demand will be measured for applicants proposing to provide services to residents of those areas as follows:

Need. The projected need for a service will be demonstrated through need-based epidemiological evidence of the incidence and prevalence of conditions for which diagnostic and/or therapeutic catheterization is appropriate within the proposed service area.

Demand. The projected demand for the service shall be determined by the following formula:

- A. Multiply the age group-specific historical state utilization rate by the number of residents in each age category for each county included in the proposed service area to produce the projected demand for each age category;
- B. Add each age group's projected demand to determine the total projected demand for cardiac catheterization procedures for the entire proposed service area.

There are currently no existing cardiac therapeutic catheterization providers in the proposed 6 county Tennessee service area. DRMC evaluated transfer data and concluded 1,021 patients were transferred from DRMC to more intensive cardiac services in 2013. In addition, DRMC estimated 214 patients by-passed DRMC to receive cardiac care outside the service area. DRMC estimated 25% of all transfer volume received a therapeutic catheterization which equals to 309 procedures. DRMC then estimated the rate of inpatient to outpatient PCI volumes were 70%/30%, but elected to take a more conservative approach of 80%/20%.

With 95% of cardiac interventions occurring in the 45+ age group,

DRMC assumed 367 of the estimated 386 PCI 2013 patients in the DRMC service area were in this age cohort. DRMC calculated a service area use rate of 2.03 per 1,000 population. DRMC projected PCI volume of 131 in Year One, 165 in Year Two and 199 in Year Three using a Projected DRMC Market Share of 33%, 42%, and 50% respectively. Please refer to Table 9 on page 24 of the application.

It appears that this criterion is met.

10. Access: In light of Rule 0720-4-.01 (1), which lists the factors concerning need on which an application may be evaluated, the HSDA may decide to give special consideration to an applicant:

- a. Who is offering the service in a medically underserved area as designated by the United States Health Resources and Services Administration;

All counties in the proposed service area encompass medical underserved areas.

It appears that this criterion is met.

- b. Who documents that the service area population experiences a prevalence, incidence and/or mortality from heart and cardiovascular diseases or other clinical conditions applicable to cardiac catheterization services that is substantially higher than the State of Tennessee average;

All six counties (Crockett, Dyer, Gibson, Lake, Lauderdale, and Obion counties) in the proposed Tennessee service area have a higher average mortality rate (all ages) higher than the State rate of 220.7 deaths per 100,000. In addition, the applicant is also declaring Pemiscot, MO in DRMC's service area, which also has a higher average mortality rate that exceeds the Missouri state rate of 209.1 deaths per 100,000. Please refer to table 3 on page 20 of the application for heart disease mortality rates.

It appears that this criterion is met.

Who is a "safety net hospital" as defined by the Bureau of TennCare Essential Access Hospital payment program;
or

The applicant is not a safety net hospital.

It appears that this criterion is not met.

- c. Who provides a written commitment of intention to contract with at least one TennCare MCO and, if providing adult services, to participate in the Medicare program.

The applicant contracts with all three TennCare MCOs in West Tennessee and participates in the Medicare program.

It appears that this criterion is met.

Applicants proposing to provide therapeutic cardiac catheterization services must meet the following minimum standards:

11. Minimum Volume Standard: Such applicants should demonstrate that the proposed service utilization will be a minimum of 400 diagnostic and/or therapeutic cardiac catheterization cases per year by its third year of operation. At least 75 of these cases per year should include a therapeutic cardiac catheterization procedure. Annual volume shall be measured based upon a two-year average which shall begin at the conclusion of the applicant's first year of operation. Only cases including diagnostic and therapeutic cardiac catheterization procedures as defined by these Standards and Criteria shall count towards meeting this minimum volume standard.

DRMC projects 524 total adult cardiac cath lab cases in Year One of which 131 procedures will be therapeutic cardiac cath.

It appears that this criterion is met.

12. Open Heart Surgery Availability: Acute care facilities proposing to offer adult therapeutic cardiac catheterization services shall not be required to maintain an on-site open heart surgery program. Applicants without on-site open heart surgery should follow the most recent American College of Cardiology/American Heart Association/Society for Cardiac Angiography and Interventions Practice Guideline Update for Percutaneous Coronary Intervention (ACC/AHA/SCAI Guidelines). As of the adoption of these Standards and Criteria, the latest version of this document (2007) may be found online at:

<http://circ.ahajournals.org/cgi/reprint/CIRCULATIONAHA.107.185159>

DRMC has transfer agreement protocols with the Regional Hospital of Jackson, Methodist University Hospital-Memphis, St. Francis-Memphis and Vanderbilt University-Nashville. In the supplemental response, the applicant attests DRMC will maintain compliance with the most recent American College of Cardiology/American Heart Association/Society for Cardiac Angiography and Interventions Practice Guideline Update for Percutaneous Coronary Intervention (ACC/AHA/SCAI Guidelines).

It appears that this criterion is met.

13. Therapeutic procedures should not be performed in freestanding cardiac catheterization laboratories, whether fixed or mobile. Mobile units may, however, perform therapeutic procedures provided the mobile unit is located on a hospital campus and the hospital has on-site open heart surgery. In addition, hospitals approved to perform therapeutic cardiac catheterizations without on-site open heart surgery backup may temporarily perform these procedures in a mobile laboratory on the hospital's campus during construction impacting the fixed laboratories.

DRMC plans to perform Percutaneous Coronary Intervention (PCI) procedures in its existing cardiac catheterization lab that is located in the hospital.

It appears that this criterion is met.

14. Minimum Physician Requirements to Initiate a New Service: The initiation of a new therapeutic cardiac catheterization program should require at least two cardiologists with at least one cardiologist having performed an average of 75 therapeutic procedures over the most recent five year period. All participating cardiologists in the proposed program should be board certified or board eligible in cardiology and any relevant cardiac subspecialties.

DRMC intends to meet minimum physician requirements and compliance.

It appears that this criterion is met.

15. Staff and Service Availability: Ideally, therapeutic services should be available on an emergency basis 24 hours per day, 7 days per week through a staff call schedule (24/7 emergency coverage). In addition, all laboratory staff should be available within 30 minutes of the activation of the laboratory. If the applicant will not be able to immediately provide 24/7 emergency coverage, the applicant should present a plan for reaching 24/7 emergency coverage within three years of initiating the service or present a signed transfer agreement with another facility capable of treating transferred patients in a cardiac catheterization laboratory on a 24/7 basis within 90 minutes of the patient's arrival at the originating emergency department.

DRMC intends to meet all the above staff and service availability requirements.

It appears that this criterion is met.

16. Expansion of Services to Include Therapeutic Cardiac Catheterization: An applicant proposing the establishment of therapeutic cardiac catheterization services, who is already an existing provider of diagnostic catheterization services, should demonstrate that its diagnostic cardiac catheterization unit has been utilized for an average minimum of 300 cases per year for the two most recent years as reflected in the data

supplied to and/or verified by the Department of Health.

According to the Department of Health Joint Annual Report, DRMC averaged 2,003 diagnostic catheterization procedures for the past two reporting years (2011-2012). However, the Joint Annual Report does not collect cardiac catheterization data by cases.

Data is not available to determine if criterion is met.

STAFF SUMMARY

Note to Agency members: This staff summary is a synopsis of the original application and supplemental responses submitted by the applicant. Any HSDA Staff comments will be presented as a "Note to Agency members" in bold italics.

Dyersburg Regional Medical Center (DRMC) is proposing to offer therapeutic cardiac catheterization, in addition to the current cardiac diagnostic service, in its existing cardiac catheterization lab. If approved, no construction or renovation to initiate therapeutic cardiac catheterization will be needed.

History

- March 22, 2006-Dyersburg Regional Medical Center's application (CN0509-083DA) for the establishment of a cardiac catheterization laboratory to provide diagnostic services was denied. A motion to reconsider the application was approved prior to the end of the meeting as permitted by statute. The application was scheduled for reconsideration at the June 28, 2006 meeting.
- June 28, 2006 -The application was denied again.
- January 22, 2007-Statutorily prescribed mediation occurred due to the DRMC appeal of the denial of the application.
- February 28, 2007-The Agency discussed the mediation including new evidence that addressed patient safety and volume. The Agency authorized the General Counsel to enter into an Agreed Order to approve the certificate of need.
- May 4, 2007-The Agreed Order granting the certificate of need was approved with the following limitations: 1) cardiac catheterization procedures are limited to diagnostic only and interventional procedures will not be provided, and 2) patients receiving cardiac catheterization are limited to those who qualify for the procedure in settings without cardiac surgery on the basis of patient exclusion criteria developed by the American College/Society for Cardiac Angiography and Interventions.

Need

The applicant indicates the addition of therapeutic catheterization services will improve access and patient outcomes and identified the following reasons the services are needed:

- Transporting patients to other facilities to receive a higher level of care results in an increase in time to be treated, increases the risk of infection or injury, and increases the cost of care.

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- Decreased treatment time in heart attack patients helps prevent irreversible heart muscle damage.
- Aged 65 and over patients often rely on family members and/or public transportation to access medical care.
- The closest therapeutic catheterization service is located 48 miles away, or 50 minutes.

Ownership

- DRMC is owned by Dyersburg Hospital Corporation, which is owned by an affiliate of Community Health Systems based in Franklin, Tennessee.
- CHS owns, operates or leases 206 hospitals in 29 states with 20 located in Tennessee.

Facility Information

- The proposed project does not require construction or renovation.
- Proposed Percutaneous Coronary Intervention (PCI) services will be performed in the existing cardiac catheterization laboratory.
- A floor plan drawing is included as Attachment B.IV. - Floor Plan to the original application.

According to the 2012 Joint Annual Report, Dyersburg Regional Medical Center is licensed for 225 beds and staffed for 120 beds. The 2012 licensed bed occupancy was 15%, while the staffed bed occupancy was 28.5%. There is no proposed change to the applicant's licensed bed complement.

Licensed Beds- The maximum number of beds authorized by the appropriate state licensing (certifying) agency or regulated by a federal agency. This figure is broken down into adult and pediatric beds and licensed isolettes (neonatal intensive or intermediate care isolettes).

Staffed Beds-The total number of adult and pediatric beds set up, staffed and in use at the end of the reporting period. This number should be less than or equal to the number of licensed beds.

The Joint Annual Reports for DRMC indicated 17,858 inpatient hospital days in 2010, 16,314 in 2011 and 12,495 in 2012, a decrease of 42% from 2010 to 2012. A bed complement chart for DRMC is included in Attachment A.9.

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Service Area Utilization

Currently, DRMC and Baptist Memorial Hospital-Union City (Obion County) are the only two hospitals with cardiac catheterization laboratories in DRMC's 7 county service area. Both hospitals offer diagnostic catheterization services, but do not have therapeutic cardiac catheterization (PCI) or open heart surgery capabilities. The reported cardiac catheterization laboratory Joint Annual Report utilization data for the latest three (3) available years is contained in the table below:

	Diagnostic Catheterization Procedures		
Hospital	2010	2011	2012
Dyersburg Regional Medical Ctr.	1,068	2,339	1,668
Baptist-Union City	54	37	31
Total	1,122	2,376	1,699

Source: 2010-2012 Joint Annual Report

Historical and Projected utilization for DRMC's Cardiac Catheterization lab utilization is provided below:

DRMC Historical and Projected Cardiac Catheterization Volumes (Cases)

	Historical			Projected	
Service	2011	2012	2013	Year 1 (2015)	Year 2 (2016)
Diagnostic Cardiac Catheterization	343	294	218	393	494
Therapeutic Cardiac Cath	0	0	0	131	165
Total Cardiac Cases	343	294	218	524	659

Source: DRMC, CN1403-007

- If approved, Diagnostic Cardiac Catheterization utilization is projected to increase 80% from 218 cases in 2013 to 393 cases in 2015.
- In Year Two, the applicant projects to perform 659 total cardiac cases, or 165% of the 400 minimum standard for diagnostic and/or therapeutic cardiac catheterization cases that is expected by Year Three.

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- The decline in diagnostic cardiac catheterization cases from 294 in 2012 to 218 in 2013 was attributed to the departure of a cardiologist from the medical staff.

Service Area Outmigration-2012

The table below reflects the migration of open heart surgery patients from the existing 7 county service area. The table indicates the following:

- Jackson-Madison County General Hospital (Madison County) experienced the highest open heart surgery volume from the proposed service area with 163 open heart surgeries, or 57.2%.
- Baptist Memorial Hospital (Shelby County) experienced the highest patient procedure volume from the DRMC service area of all Shelby County hospitals with 44 open heart surgeries, or 15.4%.
- Overall, 164 patients (57.5%) open heart patients from the service area went to Jackson (Madison County) hospitals, 76 patients (26.7%) open heart patients went to Memphis (Shelby County) hospitals, and 45 (15.8%) went to Nashville (Davidson County) hospitals.

Hospital	Hospital County Location	Open Heart Surgery	% of total
Saint Thomas Hospital	Davidson	2	0.70%
Vanderbilt University Hospitals	Davidson	29	10.2%
Centennial Medical Center	Davidson	14	4.9%
Jackson - Madison County General Hospital	Madison	163	57.2%
Regional Hospital of Jackson	Madison	1	0.35%
Baptist Memorial Hospital	Shelby	44	15.4%
Methodist Hospital - Germantown	Shelby	7	2.5%
The Regional Medical Center at Memphis	Shelby	3	1.0%
Methodist Healthcare - Memphis Hospitals	Shelby	7	2.4%
Methodist Hospital - North	Shelby	3	1.0%
Lebonheur Children's Medical Center	Shelby	10	3.5%
Saint Francis Hospital	Shelby	2	0.70%
Total		285	

Source: Tennessee Department of Health 2012 Inpatient Discharge Data, Open Heart ICD-9 codes

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Heart and Cardiovascular Mortality Rates

All six Tennessee counties in the proposed service area have a heart and cardiovascular rate higher than the state-wide rate of 220.6 per 100,000 population according to the table below.

Proposed Service Area Heart and Cardiovascular Mortality Rate

County/State	Number of Deaths	Rate
State	14,245	220.6
Crockett	52	355.7
Dyer	99	258.8
Gibson	164	330.4
Lake	25	325.2
Lauderdale	78	281.5
Obion	113	360.6

Source: http://health.state.tn.us/statistics/PdfFiles/VS_Rate_Sheets_2012/Heart2012.pdf

Service Area Demographics

DRMC's declared service area includes Crockett, Dyer, Gibson, Lake, Lauderdale, and Obion Counties in Tennessee and Pemiscot County in Missouri.

The total population of the Tennessee service area is estimated at 172,442 residents in calendar year (CY) 2014 increasing by approximately 0.2% to 172,706 in CY 2018.

- The range of growth is -1.3% in Lake County to 1.2% in Gibson County.
- Gibson County is projected to have the largest population (51,695 or 30% of total service area population) of the service area counties followed by Dyer County (38,301 or 22% of total).
- The overall statewide population is projected to grow by 1.8% from 2014 to 2018.
- In 2013, 22.8% of the service area were enrolled in TennCare while the statewide enrollment proportion was 18.1%.

Source: *The University of Tennessee Center for Business and Economic Research Population Projection Data Files, Reassembled by the Tennessee Department of Health, Division of Policy, Planning and Assessment, Office of Health Statistics.*

Equipment

DRMC plans to invest \$200,000 into the following equipment and upgrades:

- An imaging console that enhances the diagnosis of atherosclerosis (hardening of the arteries) and heart disease using intravascular ultrasound (IVUS) imaging and fractional flow reserve (FFR) software.

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- An uninterrupted power supply (UPS) in the cardiac catheterization lab to ensure no power supply is interrupted by a power failure.

Project Cost

Major costs are:

- The largest cost is \$200,000 for fixed and moveable equipment, or 54.4% of total project cost.
- The next largest cost of the proposed project is legal, administrative, and consultant fees at \$147,000 or 40% of total project cost.
- For other details on Project Cost, see the Project Cost Chart on page R-41 of the original application.

Historical Data Chart

- According to the Historical Data Chart, DRMC reported the following net operating loss/income after capital expenditures; net operating income of \$4,891,922 in 2011, \$994,347 in 2012; and \$3,839,645 for 2013.

Projected Data Chart

The Projected Data Chart for the proposed service reflects \$19,155,298 in total gross revenue on 306 cases during the first year of operation and \$26,746,067 on 440 cases in Year Two. The Projected Data Chart reflects the following:

- Net operating income less capital expenditures for the applicant will equal \$1,039,170 in Year One increasing to \$1,907,022 in Year Two.
- Net operating revenue after bad debt, charity care, and contractual adjustments is expected to be approximately 13% of total gross revenue in both Year One and Year Two, totaling \$2,487,514 and \$3,473,254, respectively.
- Gross operating margin is expected to be 5.4% in Year One and 7.1% Year Two.

Charges

In Year One of the proposed project, the average charge per procedure information is as follows:

- The proposed average gross charge per diagnostic/therapeutic cardiac procedure is \$62,599; however the net charge per procedure is \$8,129.

Medicare/TennCare Payor Mix

- The expected payor mix in Year 1 includes 75% for Medicare and 3% for TennCare.
- DRMC contracts with all TennCare MCOs in the service area.
- DRMC is also a contracted Medicaid provider with the State of Missouri.

Financing

- A March 4, 2014 letter from Meredith Malone, CFO of Dyersburg Regional Medical Center noted the availability of \$364,763 in cash reserves to fund the proposed project.
- DRMC's unaudited financial statements dated December 31, 2013 reported \$613,065 in cash, total current assets of \$11,349,709, total current liabilities of \$4,633,801 and a current ratio of 2.45:1. Current ratio is a measure of liquidity and is the ratio of current assets to current liabilities which measures the ability of an entity to cover its current liabilities with its existing current assets. A ratio of 1:1 would be required to have the minimum amount of assets needed to cover current liabilities.

Staffing

The proposed staffing for the proposed therapeutic catheterization service is displayed in the table below:

Position Type	FTE
Registered Nurse	4.0
Cardiovascular Radiology Technician	2.0

If approved, DRMC will recruit at a minimum 2 interventional cardiologists.

Licensure/Accreditation

- Dyersburg Regional Medical Center is accredited by The Joint Commission. A copy of the latest Joint Commission survey is located in Attachment C, (III) 7 (d) Joint Commission Survey.

Transfer Agreements

- The applicant has an existing transfer agreement with St. Francis Hospital in Memphis and Vanderbilt University Hospital in Nashville which offers a full complement of cardiovascular services.
- Methodist University Hospital in Memphis will provide cardiothoracic surgical coverage through an emergent transfer agreement (see March 21, 2014 Methodist letter in supplemental one).

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- A transfer agreement specific to open heart surgery with West Tennessee Health Care d/b/a Jackson Madison County General Hospital (Madison County) is not required because WTHC has in effect an auto-acceptance policy for Cardiology-STEMI transfers.

The applicant has submitted the required information on corporate documentation, lease, and manufacturer's quote including maintenance contract, and FDA approval. Staff will have a copy of these documents available for member reference at the meeting. Copies are also available for review at the Health Services and Development Agency's office.

Should the Agency vote to approve this project, the CON would expire in three years.

CERTIFICATE OF NEED INFORMATION FOR THE APPLICANT:

There are no other Letters of Intent or denied or pending applications for this applicant.

Outstanding Certificates of Need

Note: Community Health Systems, Inc. has financial interests in this project and other projects as follows:

Metro Knoxville, HMA, LLC d/b/a Tennova Healthcare-North Knoxville Medical Center, CN1211-056A, has an outstanding Certificate of Need that will expire on April 1, 2016. The CON was approved at the February 27, 2013 Agency meeting for the initiation of diagnostic cardiac catheterization services. The project involves construction and equipping of shell space within the hospital to serve as a dual cardiac catheterization/vascular lab, support areas for the lab, expanded waiting room, and additional pre-operative and post-operative space. The estimated project cost is **\$4,377,421.00**. *Project Status: Construction is scheduled to begin in September 2014, with an anticipated completion date of February 28, 2015.*

HMA Fentress County Hospital, LLC d/b/a Jamestown Regional Medical Center, CN1211-055, has an outstanding Certificate of Need that will expire on April 1, 2016. The CON was approved at the February 27, 2013 Agency meeting for the conversion of six (6) existing acute care hospital beds to swing beds located at 436 Central Avenue West, Jamestown (Fentress County). The estimated project cost is **\$30,677.00**. *Project Status: As of May 23 2014, the approved service will begin within 30 days if a Medicare number is received.*

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Lebanon HMA, d/b/a University Medical Center, CN1210-051A, has an outstanding Certificate of Need that will expire March 1, 2016. The CON was approved at the January 23, 2013 agency meeting for the initiation of linear accelerator services and acquisition of existing major medical equipment from Southeast Cancer Network, Inc. The estimated project cost is \$4,844,035.00. Project Status: *The acquisition of the linear accelerator services was completed in February 2013. Due to the CHS acquisition of HMA, the service line plan which would address the possible replacement of the linear accelerator has not been completed.*

North Knoxville Medical Center f/k/a Mercy Medical Center-North, CN1106-019A, has an outstanding Certificate of Need that will expire on 12/1/2014. The CON was approved at the October 26, 2011 Agency meeting for acquisition of a second linear accelerator for its radiation therapy department located on Mercy Medical Center-North campus located at 7551 Dannaher Way, Powell (Knox County), Tennessee 37849. The estimated project cost is \$4,694,671. Project Status Update: *This project has been delayed due to the CHS acquisition of HMA and other factors. As a result, it is likely a one year extension for this project will be requested.*

CERTIFICATE OF NEED INFORMATION FOR OTHER SERVICE AREA FACILITIES:

There are no Letters of Intent, pending or denied applications, or outstanding Certificates of Need from other health care organizations in the service area for projects similar to this application.

PLEASE REFER TO THE REPORT BY THE DEPARTMENT OF HEALTH, DIVISION OF HEALTH STATISTICS, FOR A DETAILED ANALYSIS OF THE STATUTORY CRITERIA OF NEED, ECONOMIC FEASIBILITY, AND CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE IN THE AREA FOR THIS PROJECT. THAT REPORT IS ATTACHED TO THIS SUMMARY IMMEDIATELY FOLLOWING THE COLOR DIVIDER PAGE.

PME (5/30/2014)

LETTER OF INTENT



LETTER OF INTENT TENNESSEE HEALTH SERVICES AND DEVELOPMENT AGENCY


The Publication of Intent is to be published in the State Gazette which is a newspaper of general circulation in Dyer County, Tennessee, on or before March 10, 2014 for one day.

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This is to provide official notice to the Health Services and Development Agency and all interested parties, in accordance with T.C.A. § 68-11-1601 *et seq.*, and the Rules of the Health Services and Development Agency, that: Dyersburg Regional Medical Center owned and managed by Dyersburg Hospital Corporation intends to file an application for a Certificate of Need for the expansion of its cardiac catheterization services, currently limited to diagnostic procedures, to include interventional (therapeutic) cardiac catheterization procedures, and the initiation of such services. Dyersburg Regional Medical Center is located at 400 Tickle Street, Dyersburg, Dyer County, Tennessee. Dyersburg Regional Medical Center is licensed as a general hospital by the Tennessee Board for Licensing Healthcare Facilities. The licensed bed complement of the hospital will not be affected by this proposal. No major medical equipment is involved in this proposal. The estimated project cost is \$367,763.00.

The anticipated date of filing the application is March 14, 2014.

The contact person for this project is Jerry W. Taylor, Attorney, who may be reached at: Stites and Harbison, PLLC, 401 Commerce Street, Suite 800, Nashville, Tennessee, 37219, 615-782-2228; jerry.taylor@stites.com


Signature

3-7-14
Date

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The published Letter of Intent contains the following statement pursuant to T.C.A. § 68-11-1607(c)(1). (A) Any health care institution wishing to oppose a Certificate of Need application must file a written notice with the Health Services and Development Agency no later than fifteen (15) days before the regularly scheduled Health Services and Development Agency meeting at which the application is originally scheduled; and (B) Any other person wishing to oppose the application must file written objection with the Health Services and Development Agency at or prior to the consideration of the application by the Agency.

COPY

-Application

Dyersburg

Regional

Medical Ctr.

CN1403-007

1500014003

CERTIFICATE OF NEED APPLICATION

FOR

DYERSBURG REGIONAL MEDICAL CENTER

**Expansion Of Existing Cardiac Catheterization Service
to Include Interventional Cardiac Catheterization
Procedures**

Dyer County, Tennessee

March 14, 2014

Contact Person:

**Jerry W. Taylor, Esq.
Stites & Harbison, PLLC
401 Commerce Street, Suite 800
Nashville, Tennessee 37219
615-782-2228**

SECTION A:**APPLICANT PROFILE**

1.	<u>Name of Facility, Agency, or Institution</u>			
	Dyersburg Regional Medical Center Name			
	400 Tickle Street Street or Route		Dyer County	
	Dyersburg City	TN State	38024 Zip Code	
2.	<u>Contact Person Available for Responses to Questions</u>			
	Jerry W. Taylor Name	Attorney Title		
	Stites & Harbison, PLLC Company Name	jerry.taylor@stites.com Email address		
	401 Commerce Street, Suite 800 Street or Route	Nashville TN 37219 City State Zip Code		
	Attorney Association with Owner	615-782-2228 Phone Number	615-742-0703 Fax Number	
3.	<u>Owner of the Facility, Agency or Institution</u>			
	Dyersburg Hospital Corporation Name	615-465-7000 Phone Number		
	c/o Community Health Systems Professional Services Corp., 4000 Meridian Blvd. Street or Route		Williamson County	
	Franklin City	TN State	37067 Zip Code	
4.	<u>Type of Ownership of Control (Check One)</u>			
	A. Sole Proprietorship	F. Government (State of TN or Political Subdivision)		
	B. Partnership	G. Joint Venture		
	C. Limited Partnership	H. Limited Liability Company		
	D. Corporation (For Profit) X	I. Other (Specify) _____		
	E. Corporation (Not-for-Profit)			

PUT ALL ATTACHMENTS AT THE BACK OF THE APPLICATION IN ORDER AND REFERENCE THE APPLICABLE ITEM NUMBER ON ALL ATTACHMENTS. Organizational documentation is attached as Attachment A, 4 Organizational Documentation.

5. **Name of Management/Operating Entity (If Applicable)**

N/A

Name

Street or Route

County

City

State

Zip Code

PUT ALL ATTACHMENTS AT THE END OF THE APPLICATION IN ORDER AND REFERENCE THE APPLICABLE ITEM NUMBER ON ALL ATTACHMENTS.

6. **Legal Interest in the Site of the Institution (Check One)**

A. Ownership

X

D. Option to Lease

B. Option to Purchase

E. Other (Specify) _____

C. Lease of _____ Years

PUT ALL ATTACHMENTS AT THE BACK OF THE APPLICATION IN ORDER AND REFERENCE THE APPLICABLE ITEM NUMBER ON ALL ATTACHMENTS.

A copy of the deed for the hospital property is attached as Attachment A, 6, Deed.

7. **Type of Institution (Check as appropriate--more than one response may apply)**

A. Hospital (Specify)

X

I. Nursing Home

B. General Ambulatory Surgical
Treatment Center (ASTC),

J. Outpatient Diagnostic Center

C. Multi-Specialty

K. Recuperation Center

D. ASTC, Single Specialty

L. Rehabilitation Facility

E. Home Health Agency

M. Residential Hospice

F. Hospice

N. Non-Residential Methadone
FacilityG. Mental Health Hospital
Mental Health Residential

O. Birthing Center

H. Treatment Facility

P. Other Outpatient Facility
(Specify) _____

Mental Retardation

Q. Other (Specify) _____

Institutional Habilitation Facility
(ICF/MR)

8. Purpose of Review (Check) as appropriate--more than one response may apply)

- | | | |
|------------------------------------------|---|----------------------------------------|
| A. New Institution | | G. Change in Bed Complement |
| B. Replacement/Existing Facility | | <i>[Please note the type of change</i> |
| C. Modification/Existing Facility | | <i>by underlining the appropriate</i> |
| D. Initiation of Health Care Service | X | <i>response: Increase, Decrease,</i> |
| as defined in TCA § 68-11-1607(4) | | <i>Designation, Distribution,</i> |
| (Specify) <u>Expansion of Diagnostic</u> | | <i>Conversion, Relocation]</i> |
| <u>Cardiac Cath to include Invasive</u> | | H. Change of Location |
| <u>Cardiac Cath (PCI)</u> | | I. Other (Specify) _____ |
| E. Discontinuance of OB Services | | _____ |
| F. Acquisition of Equipment | | |

[THE REMAINDER OF THIS PAGE INTENTIONALLY LEFT BLANK]

9. Bed Complement Data*Please indicate current and proposed distribution and certification of facility beds.*

	<u>Current Beds</u>		<u>Staffed</u>	<u>Beds</u>	<u>TOTAL</u>
	<u>Licensed</u>	<u>*CON</u>	<u>Beds</u>	<u>Proposed</u>	<u>Beds at Completion</u>
A. Medical	<u>147</u>	<u> </u>	<u>60</u>	<u> </u>	<u>147</u>
B. Surgical	<u>20</u>	<u> </u>	<u>15</u>	<u> </u>	<u>20</u>
C. Long-Term Care Hospital	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>
D. Obstetrical	<u>18</u>	<u> </u>	<u>18</u>	<u> </u>	<u>18</u>
E. ICU/CCU	<u>10</u>	<u> </u>	<u>10</u>	<u> </u>	<u>10</u>
F. Neonatal	<u>10</u>	<u> </u>	<u>10</u>	<u> </u>	<u>10</u>
G. Pediatric	<u>10</u>	<u> </u>	<u>4</u>	<u> </u>	<u>10</u>
H. Adult Psychiatric	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>
I. Geriatric Psychiatric	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>
J. Child/Adolescent Psychiatric	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>
K. Rehabilitation	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>
L. Nursing Facility (non-Medicaid Certified)	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>
M. Nursing Facility Level 1 (Medicaid only)	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>
N. Nursing Facility Level 2 (Medicare only)	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>
O. Nursing Facility Level 2 (dually certified Medicaid/Medicare)	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>
P. ICF/MR	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Q. Adult Chemical Dependency	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>
R. Child and Adolescent Chemical Dependency	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>
S. Swing Beds	<u>10</u>	<u> </u>	<u>0</u>	<u> </u>	<u>10</u>
T. Mental Health Residential Treatment	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>
U. Residential Hospice	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>
TOTAL	<u>225</u>	<u>0</u>	<u>117</u>	<u>0</u>	<u>225</u>

10. Medicare Provider Number: 44-0072

Certification Type: Hospital

11. Medicaid Provider Number: 44-0072

Certification Type: Hospital

12. If this is a new facility, will certification be sought for Medicare and/or Medicaid?

DRMC is an existing licensed hospital certified for both Medicare and Medicaid

13. Identify all TennCare Managed Care Organizations/Behavioral Health Organizations (MCOs/BHOs) operating in the proposed service area.

United Healthcare Community Plan

BlueCare

TennCare Select

Will this project involve the treatment of TennCare participants?

Yes

If the response to this item is yes, please identify all MCOs/BHOs with which the applicant has contracted or plans to contract.

DRMC has contracts with all three TennCare MCOs in the West Tennessee region.

Discuss any out-of-network relationships in place with MCOs/BHOs in the area.

N/A

NOTE: *Section B* is intended to give the applicant an opportunity to describe the project and to discuss the need that the applicant sees for the project. *Section C* addresses how the project relates to the Certificate of Need criteria of Need, Economic Feasibility, and the Contribution to the Orderly Development of Health Care. Discussions on how the application relates to the criteria should not take place in this section unless otherwise specified.

SECTION B: PROJECT DESCRIPTION

Please answer all questions on 8 1/2" x 11" white paper, clearly typed and spaced, identified correctly and in the correct sequence. In answering, please type the question and the response. All exhibits and tables must be attached to the end of the application in correct sequence identifying the questions(s) to which they refer. If a particular question does not apply to your project, indicate "Not Applicable (NA)" after that question.

- I. **Provide a brief executive summary of the project not to exceed two pages. Topics to be included in the executive summary are a brief description of proposed services and equipment, ownership structure, service area, need, existing resources, project cost, funding, financial feasibility and staffing.**

RESPONSE: Dyersburg Regional Medical Center ("DRMC") is a 225-bed community hospital located in Dyersburg, Tennessee. DRMC is a member of Community Health Systems, Inc. ("CHS"), which is headquartered in Franklin, Tennessee. CHS owns, operates or leases 206 hospitals in 29 states as of February 2014. As a member of CHS, DRMC is in a position to benefit from the experience gained by health system hospitals, which will be particularly useful in regards to the applicant's proposal to expand its service capabilities with this application.

DRMC serves the needs of over 190,000 people residing in a in a 7-County area in west Tennessee and Missouri. The Counties in DRMC's service area include Crocket, Dyer, Gibson, Lake, Lauderdale, and Obion Counties in Tennessee, and Pemiscot County in Missouri. Currently, DRMC is one of only two hospitals located within this 7-County area that have a cardiac catheterization lab, with neither hospital having therapeutic cardiac catheterization ("PCI") or open heart surgery capabilities. When evaluating the demographics of the DRMC service area, it is clear that the applicant is providing healthcare services to a patient population that has significantly higher rates of mortality from heart disease and acute myocardial infarctions ("AMI," "STEMI," or heart attack), higher rates of poverty, and a higher percentage of elderly when compared to the state and the nation. In addition, all of the Counties in DRMC's service area are designated as medically underserved areas ("MUAs") by the Health Resources and Services Administration ("HRSA"). MUAs are characterized by HRSA as having too few primary care providers, high infant mortality, high poverty and/or high elderly population¹. These factors contribute to a population with a heightened need for improvements to access to care that will aid in improving the health status of the community.

Patients that require treatment options beyond the scope of services offered by DRMC -- PCI or open heart surgery -- are transferred or referred to a provider based in a County outside of the

¹ "Find Shortage Areas: MUA/P by State and County," Health Resources and Services Administration, <http://muafind.hrsa.gov/index.aspx>, Accessed 23 January 2014.

service area. This situation causes delays to treatment, adds unnecessary costs to patient care with increased EMS transports over longer distances, and places residents in the DRMC service area in a situation that involves unnecessary risks. According to data from the National Registry of Myocardial Infarction ("NRMl"), patients who are transferred for primary PCI are treated 71 minutes later than patients who receive primary PCI locally. Additionally, the NRMl registry demonstrates that a door-to-balloon time of 2.5 to 3 hours, as seen in patients transferred for PCI, is associated with a 60% increase in risk-adjusted mortality compared with a door-to-balloon time of less than 2 hours². With the approval to initiate PCI services at DRMC, patients that reside in the service area would now be able to travel to a hospital offering PCI services in less than 1 hour, with the majority of residents able to travel to DRMC in less than 30 minutes.

Due to the initiation of a diagnostic cardiac catheterization service at DRMC in 2009, the applicant would require a relatively minimal investment to advance its capabilities to offer PCI. DRMC will not need to renovate its physical plant to offer the service, and therefore has no renovation or construction costs associated with this project. The total capital investment to introduce PCI services at DRMC is \$200,000. Given the relatively low cost of entry, the initiation of a PCI services would be financially viable decision for the applicant. Additionally, PCI services will allow DRMC to better utilize existing space and equipment that is already in place for the diagnostic catheterization program. At the same time, the inability to advance DRMC's capabilities to offer PCI services has the potential to cause erosion to the volume of diagnostic catheterization currently performed.

Through an evaluation of patient transfer data, it is clear that DRMC has a high volume of patients with cardiovascular disease presenting to the hospital. In fact, in 2013 alone DRMC transferred over 1,000 patients for cardiovascular reasons. With non-invasive testing and diagnostic catheterization capabilities on-site, clearly a number of patients presenting to DRMC are considered high risk or are in need of a higher level of cardiac care that is not offered at the hospital today. The market potential for an expansion in capabilities to offer PCI services indicates DRMC will meet the established volume thresholds for a PCI program within its first full year of operation. With no PCI program in the DRMC service area, DRMC, with the approval to offer PCI, will have no effect on provider volumes for those that are located in the seven counties it serves. Additionally, given the significantly high mortality rates for heart disease and AMI in the region, a new PCI program will improve access to necessary care while having a marginal effect on programs located outside of the DRMC market.

In summary, the proposed project will improve access to the recognized standard of care in the treatment of AMI, is economically feasible, provides a necessary service to Tennesseans, and reduces unnecessary risks to the patient population DRMC serves. For these reasons and more, the applicant requests that the Tennessee Health Services and Development Agency approve its application to expand its capabilities to offer therapeutic cardiac catheterization services to the communities it serves.

II. Provide a detailed narrative of the project by addressing the following items as they relate to the proposal.

² Reference: Wharton, Thomas P., "The Case for Community Hospital Angioplasty," *Circulation*. 2005; 112: 3509-3534.

- A. Describe the construction, modification and/or renovation of the facility (exclusive of major medical equipment covered by T.C.A. § 68-11-1601 et seq.) including square footage, major operational areas, room configuration, etc. Applicants with hospital projects (construction cost in excess of \$5 million) and other facility projects (construction cost in excess of \$2 million) should complete the Square Footage and Cost per Square Footage Chart. Utilizing the attached Chart, applicants with hospital projects should complete Parts A.-E. by identifying as applicable nursing units, ancillary areas, and support areas affected by this project. Provide the location of the unit/service within the existing facility along with current square footage, where, if any, the unit/service will relocate temporarily during construction and renovation, and then the location of the unit/service with proposed square footage. The total cost per square foot should provide a breakout between new construction and renovation cost per square foot. Other facility projects need only complete Parts B.-E. Please also discuss and justify the cost per square foot for this project.

If the project involves none of the above, describe the development of the proposal.

RESPONSE: Not applicable (NA). The applicant, DRMC, will not require construction or renovation to initiate therapeutic cardiac catheterization ("Percutaneous Coronary Intervention," or "PCI," or "coronary angioplasty") services, inclusive of primary and elective angioplasty. DRMC currently performs diagnostic cardiac catheterization services. PCI services will be performed in the existing cardiac catheterization laboratory.

- B. Identify the number and type of beds increased, decreased, converted, relocated, designated, and/or redistributed by this application. Describe the reasons for change in bed allocations and describe the impact the bed change will have on the existing services.

RESPONSE: Not applicable (NA). The expansion in services does not require any change in the number and type of beds.

- C. As the applicant, describe your need to provide the following health care services (if applicable to this application):

1. Adult Psychiatric Services
2. Alcohol and Drug Treatment for Adolescents (exceeding 28 days)
3. Birthing Center
4. Burn Units
5. Cardiac Catheterization Services
6. Child and Adolescent Psychiatric Services
7. Extracorporeal Lithotripsy
8. Home Health Services
9. Hospice Services
10. Residential Hospice
11. ICF/MR Services
12. Long-term Care Services
13. Magnetic Resonance Imaging (MRI)
14. Mental Health Residential Treatment
15. Neonatal Intensive Care Unit

16. Non-Residential Methadone Treatment Centers
17. Open Heart Surgery
18. Positron Emission Tomography
19. Radiation Therapy/Linear Accelerator
20. Rehabilitation Services
21. Swing Beds

RESPONSE: Since 2009, DRMC has offered diagnostic cardiac catheterization services. DRMC is proposing to offer therapeutic cardiac catheterization services, also known as percutaneous coronary intervention (“PCI”) and angioplasty, including both primary and elective cases. Due to the applicant’s inability to provide a higher level of care, patients that are considered high-risk, patients who have a history of coronary artery disease and those that present to the emergency department with an acute myocardial infarction (“heart attack,” or “AMI”), and those that require an intervention as determined through diagnostic catheterizations are referred and/or transferred to facilities that offer higher levels of cardiac care not currently provided at DRMC. This situation places patients in an undesirable and risky position for many reasons, including increasing the risk for infection or injury to the surgical access site due to transport or receiving multiple incisions, increasing the time it takes to be treated, and increasing the cost of care. Ultimately, transferring patients is not considered the “standard of care”, which in the simplest terms would entail providing therapeutic catheterization services to these patients that are otherwise transferred or bypass DRMC today.

It is in the best interests of patients experiencing a life-threatening event such as a heart attack to receive the appropriate treatment safely in the timeliest manner available. Indeed, the phrase “time is heart muscle” is used to describe the permanent irreversible damage to their myocardium (“heart muscle”) that occurs from the onset of an AMI until treatment is delivered.

Upon approval of this CON, DRMC would have the capability to save lives and improve patient outcomes by improving access to the standard of care for patients experiencing a heart attack. Currently, the closest PCI center to DRMC is approximately 48 miles away. Given the current traffic patterns and route characteristics, it takes approximately 50 minutes or more for patients to travel from DRMC to a hospital with PCI capabilities. This unnecessary travel time undoubtedly impacts patient outcomes. The ability to initiate treatment for AMI patients at the time they present to DRMC with symptoms will afford the best possible outcome.

The current national benchmark measure for timeliness of care for patients suffering from an AMI, as established by the American College of Cardiology, is “door-to-balloon” time. Currently, the accepted benchmark for door-to-balloon time, or time to reperfusion from patient presentation at the hospital, is 90 minutes or less. Nationally, all hospitals that provide primary PCI, PCI to STEMI patients, demonstrate an average door-to-balloon time of 64.5 minutes. Whereas, the average door-to-balloon time for patients requiring a transfer for care is 121 minutes.³ Nearly doubling the time to treatment from patient presentation

³ Dehmer, G.J. et al. “A Contemporary View of Diagnostic Cardiac Catheterization and Percutaneous Coronary Intervention in the United States.” JACC, 2012; 60 (20): 2017-2013.

with symptoms is simply not acceptable when the standard of care can be offered safely at DRMC. Every additional minute of not receiving timely treatment escalates the risk of patient death.

Primary angioplasty has been proven to be the treatment of choice for AMI patients, and is supported by numerous clinical trials conducted in the United States and Europe, as described below:

“In the total DANAMI-2 population and in transferred patients, the absolute 6% reduction of the composite endpoint achieved with primary angioplasty at 30 days was maintained and still highly significant after 3 years. This finding is in accordance with long-term results from the PRAGUE-2 trial. A sustained benefit of primary angioplasty during long-term follow-up was also reported from the smaller but pioneering Zwolle and PAMI trials, in which all patients, however, were admitted directly to angioplasty centers.”⁴

In addition to the benefits derived from initiating primary PCI services (PCI for AMI or STEMI patients) at DRMC, there is also a distinct clinical benefit to offering elective, or scheduled, PCI services to the population the hospital serves. Currently, when significant coronary artery disease is identified in patients receiving a diagnostic cardiac catheterization at DRMC, the patients are referred to a provider outside of the area for additional treatment options. This referral pattern causes discontinuity in patient care, creates unnecessary travel/access hardships for the patients and their families, and increases the costs of care to the patients. With approval of this application, DRMC would be in position to provide treatment options at the time of diagnosis of disease. Thus, the patient’s primary care physician and Cardiologist could follow their patients care path from admission to the hospital, through the hospital stay, and post-discharge. Additionally, patients would now be in a position to receive their care closer to home. The ability for a provider to offer elective PCI capabilities is logical when primary PCI services are initiated. In offering elective procedures, DRMC would not simply be caring for the patients with more complex needs that present to the hospital emergently, but also those that are stabilized and scheduling their procedures.

The inability to provide PCI services necessitates transfers out of the organization and will result in a delay in providing the current standard of care, increase unnecessary risks to DRMC patients, as well as have the potential to erode DRMC’s diagnostic catheterization volumes thus impacting the program’s long-term viability.

In November 2011, the ACCF/AHA/SCAI published guidelines for PCI, which change the recommendations of care appropriateness from a Class III (of no benefit or potentially harmful) to a IIb (the benefit is greater than or equal to the risk) indication. By elevating the clinical indication, the new guidelines offered further evidence from the Cardiology professional community for increasing the number of facilities that should be able to perform PCI. These societies have based their latest guidelines on the success and preliminary outcomes from the national CPORT-E trial, and have considered other national

⁴The Danish multicentre randomized study of fibrinolytic therapy vs. primary angioplasty in acute myocardial infarction (the DANAMI-2 trial): outcome after 3 years follow-up - European Heart Journal (2008) 29, 1259–1266

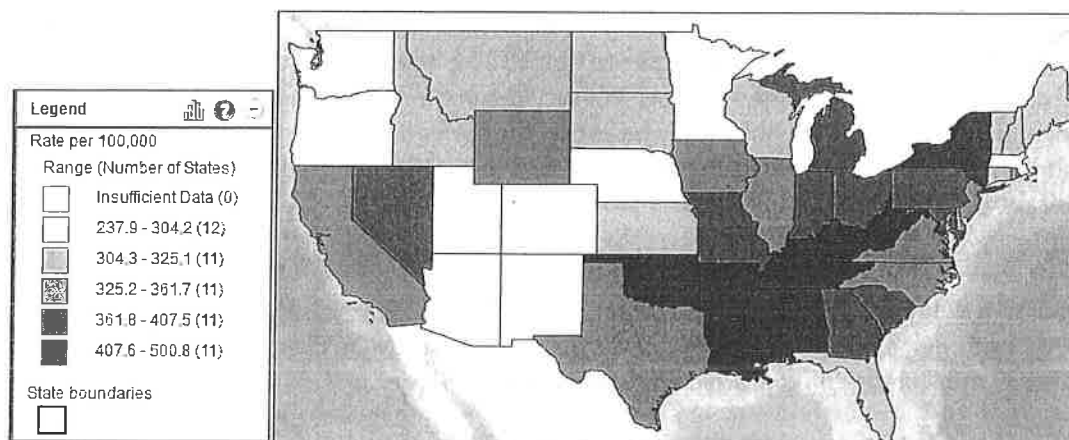
studies such as the MAYO Clinic meta-analysis⁵. The ability of an organization to reduce wait times for this necessary treatment option will reduce unnecessary patient risks.

Many patients over the age of 65 rely on family members and/or public transportation to access medical care, and increasing distance and travel time only adds greater burden. Caring for patients needs within their community alleviates the travel burden, while providing easier access-to-care, continuity-of-care, thus preventing a fragmented approach that can negatively impact outcomes. More specifically, the prevalence and risk for developing cardiovascular disease increases over the age 45, and the need for cardiovascular services is most prevalent in the over 65 age cohort. DRMC cares for an aging population in its service area, which heightens the need as a provider to ensure ease of access to care as well as continuity of care.

The impact of heart disease upon patient mortality in the state of Tennessee is concerning. In the most recent data available from the Centers for Disease Control and Prevention ("CDC"), mortality rates for heart disease are among the highest in the country. From 2008-2010, Tennessee was reported as having the *ninth highest* heart disease mortality rate when compared to other states in the country. Additionally, Tennessee had the *sixth highest* AMI mortality rate in the nation⁶.

Figure 1 below depicts the heart disease mortality rates by state in the country. It is alarming that Tennessee is in the top ten worst states as it relates to these mortality rates, and it may be indicative of a situation where access to care is an issue.

Figure 1 – Heart Disease Death Rate per 100,000, 35+, All Race, All Gender 2008-2010, USA



Source: Center for Disease Control and Prevention

When examining the statistics further, it is clear that Tennesseans have a mortality rate from heart disease that is 18.9% higher than the country. Table 1 below provides a breakdown of the heart disease mortality rates by race and ethnicity in Tennessee and the country.

⁵ Singh, Mandeep, et al. "Percutaneous Coronary Intervention at Centers With and Without On-site Surgery: A Meta-analysis." JAMA, vol 306; No.22, December 14, 2011, pages 2487-2494

⁶ Data Source: *Interactive Atlas of Heart Disease and Stroke*, a website developed by the Centers for Disease Control and Prevention, Division for Heart Disease and Stroke Prevention. <http://www.cdc.gov/dhds/maps>

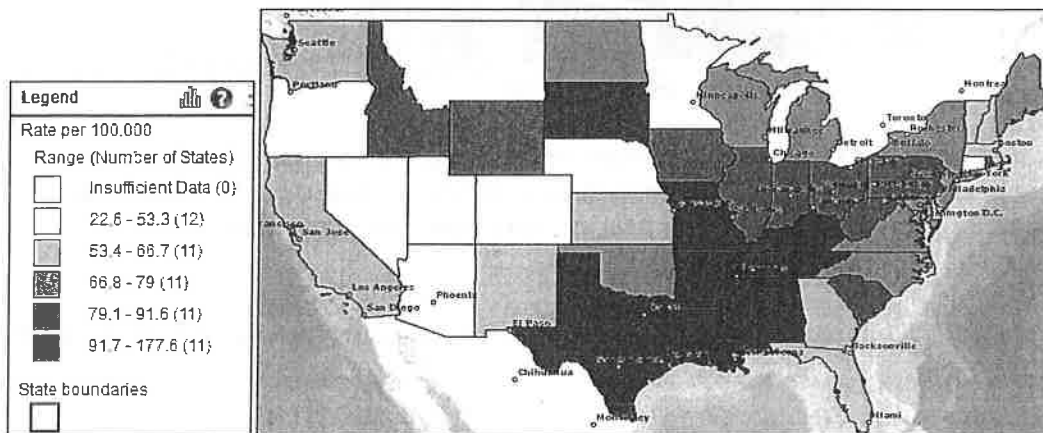
Table 1 – Heart Disease Death Rate per 100,000, 35+, All Race, All Gender, 2008-2010

Race or Ethnicity	Heart Disease Death Rate per 100,000	
	Tennessee State	United States
All Races	426.5	358.6
Black (non-Hispanic)	509.6	461.3
White (non-Hispanic)	420.8	360.3
Hispanic	120.3	266.8
American Indian and Alaskan Native	151.3	315.9
Asian and Pacific Islander	252.6	204.8

Source: Center for Disease Control and Prevention

As mentioned earlier, therapeutic catheterization procedures are considered the standard of care for patients experiencing an AMI. With the sixth highest mortality rate for AMI in the country from 2008-2010, it is likely that patients in Tennessee are not accessing or able to access care in a timely fashion. Figure 2 below depicts the mortality rate for AMI by state in the United States.

Figure 2 – Acute Myocardial Infarction (AMI) Death Rate per 100,000, 35+, All Race, All Gender 2008-2010, USA



Source: Center for Disease Control and Prevention

When examining the Tennessee mortality rate for AMI as compared to the country, it is clear that Tennesseans have experienced a mortality rate that is over 58% higher than that of the rest of the country. This is cause for significant concern, and is indicative of a need to improve patient access to treatment options for AMI. A comparison of the state rates to the country can be found in Table 2 below.

Table 2 – Acute Myocardial Infarction Death Rate per 100,000, 35+, All Race, All Gender, 2008-2010

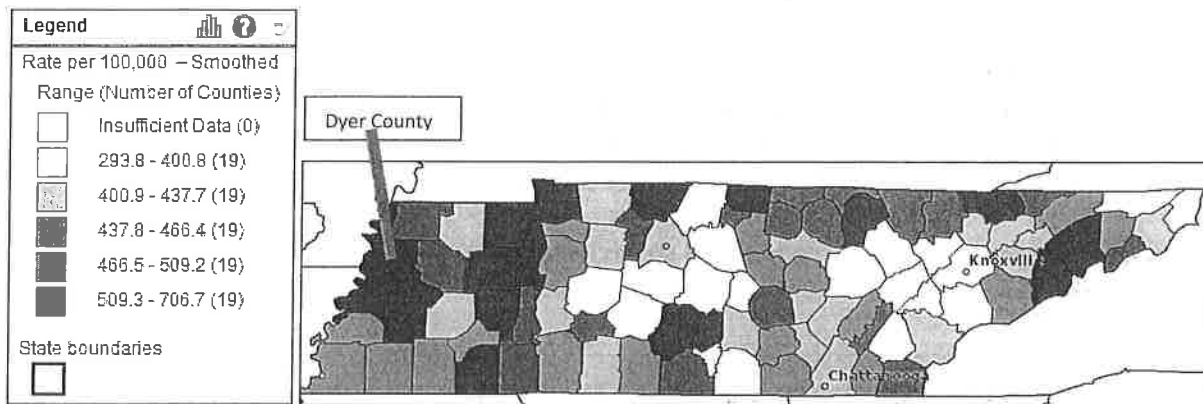
Race or Ethnicity	Acute Myocardial Infarction Death Rate per 100,000	
	Tennessee State	National
All Races	119.9	75.7
Black (non-Hispanic)	126.7	89.2
White (non-Hispanic)	121.2	77.3
Hispanic	28	59.1

American Indian and Alaskan Native	-1	68.3
Asian and Pacific Islander	82.9	44.8

Source: Center for Disease Control and Prevention

Of significant concern in DRMC's situation is the fact that the majority of Counties with relatively high heart disease mortality rates are located in west Tennessee. In fact, Dyer County has one of the highest heart disease death rates in the state. Figure 3 below illustrates the heart disease mortality rates by County within the State of Tennessee.

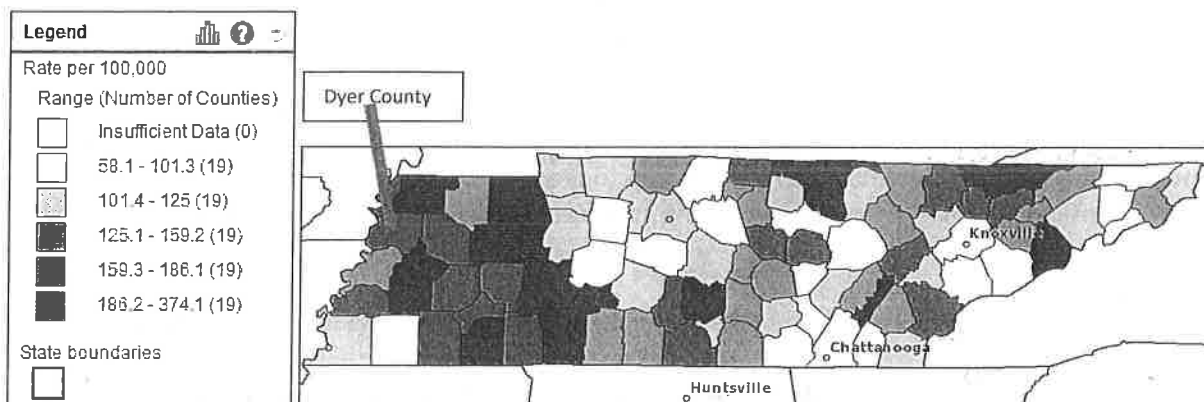
Figure 3 – Heart Disease Death Rate per 100,000, 35+, All Race, All Gender 2008-2010, Tennessee



Source: Center for Disease Control and Prevention

Correspondingly, the majority of counties in Tennessee with the highest AMI mortality rates are also located in west Tennessee. As is the case with heart disease, Dyer County also has a relatively high mortality rate for AMI. Figure 4 below illustrates AMI mortality rates by County in the State of Tennessee from 2008-2010.

Figure 4 – Acute Myocardial Infarction (AMI) Death Rate per 100,000, 35+, All Race, All Gender 2008-2010, Tennessee



Source: Center for Disease Control and Prevention

With approval of this application, it is DRMC's intent to positively impact cardiovascular patient care in the area through improved access to the recognized standard of care for AMI patients, thus positively impacting patient outcomes and mortality rates for this patient population in west Tennessee.

D. Describe the need to change location or replace an existing facility.

RESPONSE: Not applicable (NA). DRMC does not need to change location or replace an existing facility.

E. Describe the acquisition of any item of major medical equipment (as defined by the Agency Rules and the Statute) which exceeds a cost of \$1.5 million; and/or is a magnetic resonance imaging (MRI) scanner, positron emission tomography (PET) scanner, extracorporeal lithotripter and/or linear accelerator by responding to the following:

1. For fixed-site major medical equipment (not replacing existing equipment):

- a. Describe the new equipment, including:**
 - 1. Total cost; (As defined by Agency Rule).**
 - 2. Expected useful life;**
 - 3. List of clinical applications to be provided; and**
 - 4. Documentation of FDA approval.**
- b. Provide current and proposed schedules of operations.**

RESPONSE: Not applicable (NA). DRMC does not require the acquisition of fixed major medical equipment that exceeds the cost of \$1.5 million. The applicant plans to invest a total of \$200,000 into equipment, including an imaging console that enhances the diagnosis of atherosclerosis (hardening of the arteries) and heart disease using intravascular ultrasound (IVUS) imaging and fractional flow reserve (FFR) software, and an uninterrupted power supply (UPS) in the cardiac catheterization lab to ensure no power supply is interrupted by a power failure.

2. For mobile major medical equipment:

- a. List all sites that will be served;**
- b. Provide current and/or proposed schedule of operations;**
- c. Provide the lease or contract cost.**
- d. Provide the fair market value of the equipment; and**
- e. List the owner for the equipment.**

RESPONSE: Not applicable (NA). This proposal does not require the acquisition of mobile major medical equipment that exceeds the cost of \$1.5 million.

3. Indicate applicant's legal interest in equipment (i.e., purchase, lease, etc.) the case of equipment purchase include a quote and/or proposal from an equipment vendor, or in the case of an equipment lease provide a draft lease or contract that at least includes the term of the lease and the anticipated lease payments.

RESPONSE: Not applicable (NA). This proposal does not require the acquisition of major medical equipment that exceeds the cost of \$1.5 million.

III. (A) Attach a copy of the plot plan of the site on an 8 1/2" x 11" sheet of white paper which must include:

- 1. Size of site (in acres);**

2. Location of structure on the site; and
3. Location of the proposed construction.
4. Names of streets, roads or highway that cross or border the site.

Please note that the drawings do not need to be drawn to scale. Plot plans are required for all projects.

RESPONSE: A plot plan for DRMC is attached as Attachment B (III) (A) DRMC Plot Plan (B) 1. Describe the relationship of the site to public transportation routes, if any, and to any highway or major road developments in the area. Describe the accessibility of the proposed site to patients/clients.

RESPONSE: DRMC is located within 3 miles of US Highway 51, US Highway 412, and Interstate 155. All of these highways are considered major traffic thoroughfares within the DRMC service area. For this reason, DRMC is readily accessible by car and ambulance. DRMC is not on a public transportation route.

- IV. Attach a floor plan drawing for the facility which includes legible labeling of patient care rooms (noting private or semi-private), ancillary areas, equipment areas, etc. on an 8 1/2" x 11" sheet of white paper.

NOTE: DO NOT SUBMIT BLUEPRINTS. Simple line drawings should be submitted and need not be drawn to scale.

RESPONSE: Please see Attachment B (IV) DRMC Cardiac Cath Lab Floor Plan for floor plan drawing of the existing cardiac catheterization laboratory.

- V. For a Home Health Agency or Hospice, identify:

1. Existing service area by County;
2. Proposed service area by County;
3. A parent or primary service provider;
4. Existing branches; and
5. Proposed branches.

RESPONSE: Not applicable (NA). DRMC is not proposing the introduction or expansion of a Home Health Agency or Hospice.

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED

In accordance with Tennessee Code Annotated § 68-11-1609(b), "no Certificate of Need shall be granted unless the action proposed in the application for such Certificate is necessary to provide needed health care in the area to be served, can be economically accomplished and maintained, and will contribute to the orderly development of health care." The three (3) criteria are further defined in Agency Rule 0720-4-.01. Further standards for guidance are provided in the state health plan (Guidelines for Growth), developed pursuant to Tennessee Code Annotated §68-11-1625.

The following questions are listed according to the three (3) criteria: (I) Need, (II) Economic Feasibility, and (III) Contribution to the Orderly Development of Health Care. Please respond to each question and provide underlying assumptions, data sources, and methodologies when appropriate. Please type each question and its response on an 8 1/2" x 11" white paper. All exhibits and tables must be attached to the end of the application in correct sequence identifying the question(s) to which they refer. If a question does not apply to your project, indicate "Not Applicable (NA)."

QUESTIONS

NEED

1. Describe the relationship of this proposal toward the implementation of the State Health Plan and Tennessee's Health: Guidelines for Growth.
 - a. Please provide a response to each criterion and standard in Certificate of Need Categories that are applicable to the proposed project. Do not provide responses to General Criteria and Standards (pages 6-9) here.

Standards and Criteria Regarding Certificate of Need Applications for All Cardiac Catheterization Services

Applicants proposing to provide any type of cardiac catheterization services must meet the following minimum standards:

1. **Compliance with Standards:** The Division of Health Planning is working with stakeholders to develop a framework for greater accountability to these Standards and Criteria. Applicants should indicate whether they intend to collaborate with the Division and other stakeholders on this matter.

RESPONSE: DRMC will remain compliant and accountable to the fore mentioned standards and criteria. DRMC intends to collaborate with the division and the other stakeholders.

2. **Facility Accreditation:** If the applicant is not required by law to be licensed by the Department of Health, the applicant should provide documentation that the facility is fully accredited or will pursue accreditation by the Joint Commission or another appropriate accrediting authority recognized by the Centers for Medicare and Medicaid Services (CMS).

RESPONSE: DRMC is fully accredited by the Joint Commission, and is licensed and in good standing with the Department of Health.

3. **Emergency Transfer Plan:** Applicants for cardiac catheterization services located in a facility without open heart surgery capability should provide a formalized written protocol for immediate and efficient transfer of patients to a nearby open heart surgical facility (within 60 minutes) that is reviewed/tested on a regular (quarterly) basis.

RESPONSE: DRMC possesses a formalized agreement for the immediate and efficient transfer of patients who, in the unlikely event, would require a rapid transport to a facility with on-site open heart

surgery. DRMC will remain in compliance with the 60 minutes transfer time as well review and test this transfer process on a quarterly basis. DRMC included a copy of the transfer agreement in Attachment C Specific Cardiac Cath Criteria (3) DRMC Transfer Agreements.

4. **Quality Control and Monitoring:** Applicants should document a plan to monitor the quality of its cardiac catheterization program, including, but not limited to, program outcomes and efficiency. In addition, the applicant should agree to cooperate with quality enhancement efforts sponsored or endorsed by the State of Tennessee, which may be developed per Policy Recommendation 2.

RESPONSE: DRMC will maintain compliance respective to program quality control and monitoring. DRMC will be participating and submitting to the American College of Cardiology's National Cardiovascular Data Registry CathPCI registry to monitor its quality and outcomes relative to peer hospitals across the country. DRMC will agree and cooperate with all efforts related to quality enhancements as sponsored by the State of Tennessee.

5. **Data Requirements:** Applicants should agree to provide the Department of Health and/or the Health Services and Development Agency with all reasonably requested information and statistical data related to the operation and provision of services and to report that data in the time and format requested. As a standard of practice, existing data reporting streams will be relied upon and adapted over time to collect all needed information.

RESPONSE: DRMC agrees to provide the Department of Health with all requested information and statistical data relevant to the operation and provisions of PCI services. DRMC will report that data within the format and time requested.

6. **Clinical and Physical Environment Guidelines:** Applicants should agree to document ongoing compliance with the latest clinical guidelines of the American College of Cardiology/Society for Cardiac Angiography and Interventions Clinical Expert Consensus Document on Cardiac Catheterization Laboratory Standards (ACC Guidelines). As of the adoption of these Standards and Criteria, the latest version (2001) may be found online at:

<http://www.acc.org/qualityandscience/clinical/consensus/angiography/dirIndex.htm>.

Where providers are not in compliance, they should maintain appropriate documentation stating the reasons for noncompliance and the steps the provider is taking to ensure quality. These guidelines include, but are not limited to, physical facility requirements, staffing, training, quality assurance, patient safety, screening patients for appropriate settings, and linkages with supporting emergency services.

RESPONSE: DRMC will maintain compliance with and documentation of those requirements as outlined by the most current guidelines as published by the American College of Cardiology, and the Society for Cardiac Angiography and Interventions. Additionally, DRMC will maintain compliance with all guidelines related to physical facility requirements, staffing, training, quality assurance, patient safety, screening patients for appropriate settings, and linkages with the supporting emergency services.

7. **Staffing Recruitment and Retention:** The applicant should generally describe how it intends to maintain an adequate staff to operate the proposed service, including, but not limited to, any plans to partner with an existing provider for training and staff sharing.

RESPONSE: DRMC plans to utilize its relationship to other CHS hospitals to access training for the existing staff at the hospital caring for cardiac catheterization lab patients. This training will ensure that the DRMC staff is prepared to care for the specific needs of PCI patients. In addition, DRMC plans to recruit additional, experienced personnel to complement the existing staff that is already in place. The experienced personnel will be employed prior to the start of the PCI program to ensure all appropriate and experienced staff is in place to care for a new patient type at the hospital.

8. Definition of Need for New Services: A need likely exists for new or additional cardiac catheterization services in a proposed service area if the average current utilization for all existing and approved providers is equal to or greater than 70% of capacity (i.e., 70% of 2000 cases) for the proposed service area.

RESPONSE: This application is not intended to increase the capacity of cardiac catheterization labs in the DRMC service area. Rather, this application is intended to allow DRMC to advance its service offerings within its existing cardiac catheterization lab. Through approval of the application, DRMC will be in a position to better utilize the capacity that exists within the current cardiac catheterization lab. Additionally, none of the hospitals within DRMC's seven-County service area currently have PCI capabilities. Therefore, the initiation of PCI services at DRMC will have no effect on volumes of existing providers within the service area.

9. Proposed Service Areas with No Existing Service: In proposed service areas where no existing cardiac catheterization service exists, the applicant must show the data and methodology used to estimate the need and demand for the service. Projected need and demand will be measured for applicants proposing to provide services to residents of those areas as follows:

Need. The projected need for a service will be demonstrated through need-based epidemiological evidence of the incidence and prevalence of conditions for which diagnostic and/or therapeutic catheterization is appropriate within the proposed service area.

Demand. The projected demand for the service shall be determined by the following formula:

- A. Multiply the age group-specific historical state utilization rate by the number of residents in each age category for each county included in the proposed service area to produce the projected demand for each age category;
- B. Add each age group's projected demand to determine the total projected demand for cardiac catheterization procedures for the entire proposed service area.

RESPONSE: Determining the need for an expansion to include PCI capabilities at DRMC included evaluating the service area demographics, understanding the incidence and mortality rates from heart disease and AMI, and determining the current availability and ease of access to these services.

DRMC's service area population is projected to grow by 1% over the next 5 years. This growth is supported by significant growth in the 65 and older age cohort. Based on resident population projections developed by the Tennessee State Data Center, DRMC's service area population ages 19 and over (adult population) is expected to reach more than 143,000 by 2018, an increase of 2%. The population in the 65 and older age cohort in DRMC's service area is growing considerably and accounts for a substantial portion of the total population. In fact, DRMC's service area population in this age cohort is expected to grow by approximately 12 percent over the next five years. People aged 65 and over are at greater risk for cardiovascular disease compared to the younger population, and thus the

demand for advanced cardiac services is greater in this age cohort. This elderly population is typically averse to travel long distances for care, which may be due to their increased need to engage family member assistance to make the trip. Traveling outside of their community for cardiac care that can be provided safely closer to home is a hardship this population should not have to endure. Clearly, adding PCI services at DRMC will alleviate this travel hardship for patients and their families.

The population in DRMC's proposed service area is not only older, but in a lower income bracket, on average when compared to the majority of Tennessee citizens, as evidenced by a high unemployment rate, a relatively low median income, and a relatively high percentage of Medicaid patients seeking care at DRMC. In 2013, DRMC's hospital payor mix included 22% of patients covered by Medicaid. Additionally, residents in the service area suffer from some of the highest heart disease and heart attack mortality rates in the country. These determinants of health significantly impact access to care, as service area residents are challenged by high rates of heart disease, in a largely elderly population, that has a relatively low income when compared to other regions in Tennessee.

DRMC's service area includes some of the poorest counties in Tennessee and Missouri. Out of the ninety-five Counties in Tennessee, Lake County ranks first in percent of people living in poverty at 43.7%, and Lauderdale County ranks fourth at 30.7%. Additionally, Pemiscot County in Missouri ranks second in Missouri counties with 30% of residents living in poverty. All counties in DRMC's proposed service area have higher percentages of the population living in poverty than the state of TN, the state of MO, and the U.S. Congruently, all counties in the service area have a lower median income than TN, MO, and the U.S., and all DRMC service area counties have populations with lower percentages with high school graduates than the state and U.S.

The median household income for residents of Lake County is only \$23,441, which is the second lowest median income for counties in Tennessee. Likewise, Pemiscot County has the second lowest median household income for counties in Missouri at only \$26,647 annually. All counties in the proposed service area are lower than the \$42,943 Tennessee annual median household income. The low income, coupled with high unemployment rates places residents in challenging situations, particularly when they are being told to travel roughly an hour away from home to receive advanced cardiac services that can safely be offered close to home.

With almost 43,000 deaths, heart disease is the leading cause of death in Tennessee⁷. The population living in the proposed service area experiences prevalence and mortality of heart disease that is substantially higher than the State of Tennessee and national averages. In fact, the counties in DRMC's proposed service area rank in the highest quartile of heart disease mortality in the state of Tennessee, and all of the service area counties have higher heart disease mortality rates than Tennessee and the United States. In DRMC's proposed service area, Crockett County ranks first in Heart Disease Mortality out of all 95 Tennessee Counties with a mortality rate of 395.8 per 100,000 people⁸. Pemiscot County, Missouri has the second highest mortality rate in DRMC's proposed service area with a rate of 326.9 per 100,000 people. The remaining DRMC service area counties have heart disease mortality rates above 250 per 100,000 people, which are higher than the state of Tennessee, Missouri, and the United States mortality rates. Furthermore, the hospitalization rate of residents in all counties but one is higher than the state of Tennessee. Table 3 below depicts the heart disease death rates, rankings, and hospitalization in the proposed service area, Tennessee, Missouri, and the United States, and Table 4

⁷ Data Source: TN DH Statistics 2007-2009

⁸ Data Source: TN DH Office of Policy, Planning & Assessment Surveillance, Epidemiology, and Evaluation, Dec 2011

depicts AMI mortality rates and rankings in the proposed service area, Tennessee, Missouri, and the United States.

Table 3 – Heart Disease Mortality Rates, Rankings, and Hospitalization, Dyersburg Regional Medical Center Proposed Service Area, Tennessee (2011), Missouri, USA 2008-2010⁹

Area	County	Heart Disease					Hospitalization
		Mortality - All Ages	Mortality Ranking (1= highest) in State (TN) - All Ages <small>Total Counties TN=94, MO=115</small>	Mortality - Ages 35+	Mortality Ranking (1= highest) in State - Ages 35+ <small>Total Counties TN=94, MO=115</small>	Mortality Ranking (1= highest) in USA - Ages 35+	
Proposed Service Area	Crockett, TN	395.8	1	706.7	1	13	1,631.1
	Dyer, TN	250.4	35	550.3	9	155	2,146.2
	Gibson, TN	245.3	38	503.9	24	318	1,572.3
	Lake, TN	262.8	25	534.1	15	207	2,762.6
	Lauderdale, TN	279.4	15	537.8	13	144	1,827.8
	Obion, TN	253.6	33	509.2	20	291	1,305.3
	Pemiscot, MO	326.9	N/A	618.6	6	42	N/A
State & U.S	State of TN	220.7	N/A	426.5	N/A	9	1,306.8
	State of MO	209.1	N/A	405.4	N/A	13	N/A
	United States	190.6	N/A	358.6	N/A	N/A	N/A

Table 4 – AMI Mortality Rates& Rankings, Dyersburg Regional Medical Center Proposed Service Area, Tennessee (2011), Missouri, USA 2008-2010¹⁰

Area	County	AMI (Acute Myocardial Infarction) – Heart Attack		
		Mortality - Ages 35+	Mortality Ranking (1= highest) in State - Ages 35+ <small>Total Counties TN=94, MO=115</small>	Mortality Ranking (1= highest) in USA - Ages 35+
Proposed Service Area	Crockett, TN	201.0	17	151
	Dyer, TN	160.8	36	444
	Gibson, TN	164.1	30	405
	Lake, TN	162.5	33	848
	Lauderdale, TN	156.8	43	480
	Obion, TN	249.7	10	70

⁹ Data Sources: for Mortality All Ages and Hospitalization: Chronic Health Profile Regions and Counties: Tennessee, TN Department of Health Office of Policy, Planning & Assessment Surveillance, Epidemiology and Evaluation; for Mortality Ages 35+: National Vital Statistics System from National Center for Health Statistics via CDC

¹⁰ Data Source: National Vital Statistics System from National Center for Health Statistics via CDC

	Pemiscot, MO	365.3	114	14
State & U.S	State of TN	119.9	N/A	6
	State of MO	120.0	N/A	5
	United States	75.7	N/A	N/A

With some of the highest heart disease and AMI mortality rates in the country, residents in DRMC's proposed service area are in great need for access to advanced cardiovascular care. Since "time is muscle," and delayed treatment equates to greater risk for permanent irreversible damage to heart muscle, it is paramount that DRMC's proposed service area population have access to treatment as quickly as possible. The excerpt below from "The Case for Community Hospital Angioplasty" illustrates this fact in more detail:

"The mortality benefit of primary PCI decreases as the time delay to PCI increases, and this benefit may disappear when the delay to PCI is more than 1 hour compared with the time to administration of a fibrinolytic agent. Patients in the United States who are transferred for primary PCI are treated 71 minutes later than patients who receive primary PCI locally (171 versus 100 minutes), according to data from the NRMI [National Registry of Myocardial Infarction]. This same NRMI registry demonstrates that a door-to-balloon time of 2.5 to 3 hours, as seen in patients transferred for PCI, is associated with a 60% increase in risk-adjusted mortality compared with <2 hours from door to balloon time."¹¹

If DRMC were to add PCI services, all residents living in DRMC's proposed service area would have access to PCI services in less than a 1 hour drive, and most would be able to get to DRMC in less than 20-30 minutes.¹² Table 5 below depicts the distance between DRMC and the two closest providers with PCI capabilities.

Table 5 – Distance and Travel time from Dyersburg Regional Medical Center to Nearest PCI Centers & Cardiac Services Available¹³

Hospital Name	Address	Miles from Dyersburg Regional Medical Center	Driving Time from Dyersburg Regional Medical Center	Major Roads	Cardiac Services Available		
					Open Heart Surgery	Diagnostic Cath	Therapeutic Cath
<i>Dyersburg Regional Medical Center</i>	<i>400 East Tickle Street, Dyersburg, TN 38024</i>	N/A	N/A	N/A	No	Yes	No
Regional Hospital of Jackson	367 Hospital Boulevard Jackson, TN 38305	47.8 miles	51 minutes	US-412 E	No	Yes	Yes

¹¹ Reference: Wharton, Thomas P., "The Case for Community Hospital Angioplasty," *Circulation*. 2005; 112: 3509-3534.

¹² Data Source: Google Maps

¹³ Data Source: Google Maps, 2012 Tennessee Joint Annual Report

Jackson-Madison County General Hospital	620 Skyline Drive Jackson, TN 38301	48.4 miles	55 minutes	TN-20 E	Yes	Yes	Yes
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Emergency Medical Service (EMS) providers are able to shorten access times using ambulances and, in some cases, air transport. However, the cost of EMS transport to patients is significant and adds to the overall cost of care for patients. It cannot be understated that across the country many EMS providers have taken a more active role in the facilitation of triaging and critically managing chest pain patients. Their direct involvement in the care and management of this patient population has become a driving force as many states are recognizing and addressing the need for these providers to transport these patients to the closest STEMI center.

From this information, DRMC believes the need for a service expansion exists within its service area. When evaluating the demand for PCI procedures at DRMC, the hospital attempted to proceed using the demand methodology outlined in this question. Through several requests, it was clear that patient utilization statistics by age cohort was not available from the Tennessee Department of Health. In absence of this data, DRMC attempted to request patient origin data at a ZIP code and/or County level by procedure code by which to develop patient utilization statistics. Unfortunately, this data was also unavailable. In absence of this data, DRMC estimated the demand for PCI procedures using an approach that was focused on patient transfer data that is tracked by DRMC and area EMS providers. The methodology when using these data sets is listed in the following section.

To project patient volumes for an expansion to offer PCI at DRMC, the applicant analyzed patient transfer data from the hospital records and that of EMS ground and air transfer providers in Dyersburg, Tennessee. The ground transport EMS provider, Dyersburg Regional Emergency Medical Services, services patients in the Dyer County market, whereas the air transport provider is based in Dyersburg, Tennessee and services a 60-mile radius surrounding their location.

Through an evaluation of this transfer data, it is clear that over 1,000 patients left DRMC for cardiovascular care in 2013, with an average of over 900 such transfers per year for the past 3 years. The primary reason that patients would be transferred from DRMC to other facilities for cardiac care is the lack of current capabilities at the hospital. As it relates to cardiac services, PCI and open heart surgery capabilities represent the significant gaps in the current services offered. The volume of ground and air transfers from DRMC for cardiac reasons for the previous three years can be found in Table 6 below.

Table 6 – Volume of Ground and Air Transfers for Cardiac Reasons from DRMC

Mode of Transfer	2011	2012	2013*
EMS Ground Transfer	777	935	1,018
EMS Air Transfer	(not available)	2	3
Total Transfers	777**	937	1,021

*EMS Ground Transfer data was annualized for 2 months, and EMS Air Transfer data for 3 months for 2013.

**Total volume of transfers in 2011 is not reflective of EMS Air Transfer volume as it was not available.

In addition to the volume of transfers from DRMC, there are also patients that EMS providers transfer from the area without first stopping at DRMC. This may be due to the patient's history, condition,

and/or preference. If an EMS provider suspects a patient is having a heart attack, the provider will bypass DRMC and bring the patient to the nearest hospital that offers PCI services. Upon approval to expand services at DRMC to offer PCI, EMS providers would not need to drive by DRMC if it were the nearest hospital as it would then be able to provide the recognized standard of care to patients experiencing an AMI. Table 7 below displays the volume of patients transported from Dyer County to providers outside of the DRMC service area for cardiac care.

Table 7 – Volume of Patients Transported via EMS from Dyer County for Cardiac Reasons without Receiving Care at DRMC

Mode of Transport	2011	2012	2013*
EMS Ground Transport	102	132	170
EMS Air Transport	(not available)	47	44
Total Transports	102**	179	214

*EMS Ground Transfer data was annualized for 2 months, and EMS Air Transfer data for 3 months for 2013.

**Total volume of transports in 2011 is not reflective of EMS Air Transfer volume as it was not available.

It is unclear what services were provided to each of the patients that were transferred in the data above. However, it is reasonable to assume that these patients were transferred to receive a higher level of cardiac care not available at DRMC (e.g., open heart surgery, coronary angioplasty), were deemed too high-risk for DRMC, and/or were managed medically at the receiving hospital. As a conservative approach to this transfer volume, DRMC assumed that just 25% of this patient population received a therapeutic catheterization procedure. Using this assumption, 309 patients transferred from DRMC or Dyer County via EMS providers would have had a PCI procedure performed in 2013. This total does not include the volume of patients that would have received an elective PCI procedure as an outpatient. As is the case with a number of other procedure types, patients receiving PCI procedures continue to migrate to an outpatient setting for their care. Although the rate of inpatient to outpatient PCIs can be 70%/30% respectively, DRMC projected a more conservative estimate of 80%/20% for these volume projections. If we assume that the 309 patients is representative of the 80% complement, then the total inpatient and outpatient PCI patients would total 386 for 2013. With roughly 95% of cardiac interventions occurring in the above 45 age cohort, it can be assumed that 367 of the 386 PCI patients were in this age cohort. It is important to note that this projection does not include patients that reside in other service area Counties that bypassed DRMC as well, due to the EMS transfer data not being available. For this and other reasons, 386 PCIs is deemed to be a conservative estimate of the market for PCI volumes in the DRMC service area.

When evaluating the validity of these volume projections, DRMC compared the utilization rate based on these calculations in the service area to that of the country. Table 8 below provides a comparison of utilization rates within the DRMC service area to the nation.

Table 8 – 2013 PCI Utilization Rates in DRMC Service Area and the Nation

2013 Service Area Population	190,186
2013 Estimated PCI Procedures in DRMC Service Area	386
Service Area Utilization Rate for PCI (per 1,000 population)	2.03
National Utilization Rate for PCI* (per 1,000 population)	2.80

*Represents a calculated utilization rate based upon 2011 discharge data derived from AHRQ HCUPNet; Population sourced from U.S. Census data for 2011.

As can be seen from Table 8 above, this approach to projecting PCI volumes is considered reasonable and conservative. Although DRMC anticipates positively impacting the relatively low utilization rates for PCI, the volume projection methodology for a new program at DRMC did not incorporate a growth in the calculated utilization rate. Rather, the rate of 2.03 PCI per 1,000 of the population was applied to the population projections for the area to determine the market potential for a PCI program at DRMC. Therefore, any growth in market potential is based directly on the projected changes in the service area population.

When projecting potential PCI patient volumes, DRMC's ability to attract patients for these services is expected to grow over time. Although the vast majority of patients transferred from the area are seeking care at DRMC first, the hospital assumes that it will need to develop a reputation for this new service. Therefore, DRMC assumed it would capture one-third of the projected market potential in its first year of operation, growing to one half of the potential by the third year of operation. Details of this volume projection methodology can be found in Table 9 below.

Table 9 – DRMC PCI Volume Projections

	2013		Year 1 (2015)	Year 2 (2016)	Year 3 (2017)
PCI Volume in DRMC Service Area	386		392	395	398
Projected DRMC Market Share	0%		33%	42%	50%
DRMC PCI Volume	0		131	165	199

When analyzing the market potential for PCI services in the service area, it is clear that the demand exists for this service at DRMC. Using this methodology, DRMC is projected to exceed the minimum volume thresholds of 400 diagnostic/therapeutic cardiac catheterizations with at least 75 being therapeutic within the 1st year of operation with the initiation of a PCI program. For this reason, DRMC meets the market demand requirements for an expansion in capabilities to offer PCI.

10. Access: In light of Rule 0720-4-.01 (1), which lists the factors concerning need on which an application may be evaluated, the HSDA may decide to give special consideration to an applicant:

- a. Who is offering the service in a medically underserved area as designated by the United States Health Resources and Services Administration;
- b. Who documents that the service area population experiences a prevalence, incidence and/or mortality from heart and cardiovascular diseases or other clinical conditions applicable

to cardiac catheterization services that is substantially higher than the State of Tennessee average;

c. Who is a “safety net hospital” as defined by the Bureau of TennCare Essential Access Hospital payment program; or

d. Who provides a written commitment of intention to contract with at least one TennCare MCO and, if providing adult services, to participate in the Medicare program.

RESPONSE:

a. DRMC is proposing to offer diagnostic and therapeutic cardiac catheterization services in medically underserved areas (“MUAs”) as designated by the Health Resources and Services Administration (“HRSA”). As of January 2014, all counties within DRMC’s proposed service area – Crockett-TN, Dyer-TN, Lake-TN, Lauderdale-TN, Obion-TN, and Pemiscot-MO Counties – are designated MUAs, “which are areas or populations designated by HRSA as having: too few primary care providers, high infant mortality, high poverty and/or high elderly population.”¹⁴ This further emphasizes the need for advanced cardiovascular care services for residents in the areas surrounding DRMC.

b. As referenced in the preceding question, the service area population that DRMC serves has a high incidence/mortality from heart disease when compared to the state and the country.

c. DRMC is not designated as a “safety net hospital”.

d. DRMC commits to fulfilling this commitment, and continuing to provide services to TennCare and Medicare patients.

Specific Standards and Criteria for the Provision of Therapeutic Cardiac Catheterization Services. Applicants proposing to provide therapeutic cardiac catheterization services must meet the following minimum standards:

14. Minimum Volume Standard: Such applicants should demonstrate that the proposed service utilization will be a minimum of 400 diagnostic and/or therapeutic cardiac catheterization cases per year by its third year of operation. At least 75 of these cases per year should include a therapeutic cardiac catheterization procedure. Annual volume shall be measured based upon a two-year average which shall begin at the conclusion of the applicant's first year of operation. Only cases including diagnostic and therapeutic cardiac catheterization procedures as defined by these Standards and Criteria shall count towards meeting this minimum volume standard.

RESPONSE: DRMC anticipates meeting the established requirement of 400 diagnostic and/or therapeutic catheterizations cases per year in its first year of operation. Additionally, in its first year of operation, DRMC projects the volume of therapeutic catheterization procedures to total 131. These volume projections satisfy the minimum volume standards referenced above.

Table 10 below displays the applicant’s volume statistics and subsequent impact on lab utilization for the past three years with the projected volumes and annual utilization for each of the first two years following the initiation of therapeutic catheterization services at DRMC.

¹⁴ “Find Shortage Areas: MUA/P by State and County,” Health Resources and Services Administration, <http://muafind.hrsa.gov/index.aspx>, Accessed 23 January 2014.

June 23, 2014**12:30 pm****Table 10 – DRMC’s Historic and Projected Cardiac Catheterization Volumes and Lab Utilization**

Dyersburg Regional Medical Center Utilization Statistics	HISTORIC			PROJECTED	
Service	2011	2012	2013	Year 1	Year 2
Diagnostic Cardiac Cath	343	294	218	393	494
Therapeutic Cardiac Cath	0	0	0	131	165
Total Adult Cardiac Cath Lab Cases	343	294	218	524	659
DRMC Cardiac Cath Labs	1	1	1	1	1
Volume of Weighted Cases Available (2,000 per lab)	2,000	2,000	2,000	2,000	2,000
DRMC Weighted Cases	343	294	218	655	824
Lab Utilization	17.2%	14.7%	10.9%	32.8%	41.2%

* The decline in volume in 2012 and 2013 was due to the departure of a Cardiologist from the medical staff. From May 2012 through August 2013, DRMC had one full-time Cardiologist on active staff at the hospital. In August 2013, a second full-time Cardiologist joined the active staff at DRMC.

15. Open Heart Surgery Availability: Acute care facilities proposing to offer adult therapeutic cardiac catheterization services shall not be required to maintain an on-site open heart surgery program. Applicants without on-site open heart surgery should follow the most recent American College of Cardiology/American Heart Association/Society for Cardiac Angiography and Interventions Practice Guideline Update for Percutaneous Coronary Intervention (ACC/AHA/SCAI Guidelines). As of the adoption of these Standards and Criteria, the latest version of this document (2007) may be found online at: <http://circ.ahajournals.org/cgi/reprint/CIRCULATIONAHA.107.185159> Therapeutic procedures should not be performed in freestanding cardiac catheterization laboratories, whether fixed or mobile. Mobile units may, however, perform therapeutic procedures provided the mobile unit is located on a hospital campus and the hospital has on-site open heart surgery. In addition, hospitals approved to perform therapeutic cardiac catheterizations without on-site open heart surgery backup may temporarily perform these procedures in a mobile laboratory on the hospital's campus during construction impacting the fixed laboratories.

RESPONSE: DRMC will maintain a formal transfer agreement with an open heart tertiary center as referenced above in number 3 from the “Standards and Criteria Regarding Certificate of Need Applications for All Cardiac Catheterization Services” DRMC will maintain compliance with the most recent American College of Cardiology/American Heart Association/Society for Cardiac Angiography and Interventions Practice Guideline Update for Percutaneous Coronary Intervention. (ACC/AHA/SCAI Guidelines). Additionally, DRMC plans to perform PCI procedures in its existing cardiac catheterization lab that is currently located within the hospital’s facility.

16. Minimum Physician Requirements to Initiate a New Service: The initiation of a new therapeutic cardiac catheterization program should require at least two cardiologists with at least one cardiologist having performed an average of 75 therapeutic procedures over the most recent five year

period. All participating cardiologists in the proposed program should be board certified or board eligible in cardiology and any relevant cardiac subspecialties.

RESPONSE: DRMC intends to maintain compliance regarding the minimum physician requirements of at least two (2) interventional cardiologists with at least one having performed an average of 75 therapeutic cardiac procedures over the most recent five year period. DRMC affirms the cardiologists that will be providing therapeutic cardiac service will be either board eligible or board certified in cardiology and other relevant cardiac subspecialties. Several interventional Cardiologists that meet these guidelines have expressed an interest in working at a new PCI program at DRMC, but without the approval to proceed it is deemed premature at this point to contract with these eligible physicians.

17. Staff and Service Availability: Ideally, therapeutic services should be available on an emergency basis 24 hours per day, 7 days per week through a staff call schedule (24/7 emergency coverage). In addition, all laboratory staff should be available within 30 minutes of the activation of the laboratory. If the applicant will not be able to immediately provide 24/7 emergency coverage, the applicant should present a plan for reaching 24/7 emergency coverage within three years of initiating the service or present a signed transfer agreement with another facility capable of treating transferred patients in a cardiac catheterization laboratory on a 24/7 basis within 90 minutes of the patient's arrival at the originating emergency department.

RESPONSE: DRMC intends to maintain compliance in assuring all staff being available and on-site within 30 minutes of activation to care for an acute myocardial infarction (AMI) patient. DRMC intends to provide 24/7 emergency coverage at the outset of the PCI program. In addition, DRMC will ensure the transfer agreement for PCI is in place with another facility capable of treating transferred patients in a cardiac catheterization lab with 24/7 coverage.

18. Expansion of Services to Include Therapeutic Cardiac Catheterization: An applicant proposing the establishment of therapeutic cardiac catheterization services, who is already an existing provider of diagnostic catheterization services, should demonstrate that its diagnostic cardiac catheterization unit has been utilized for an average minimum of 300 cases per year for the two most recent years as reflected in the data supplied to and/or verified by the Department of Health.

RESPONSE: DRMC will demonstrate the ability to maintain the minimum volume requirement as defined by the Department of Health. In 2012, DRMC did not meet this established volume threshold due to the departure of a Cardiologist from the medical staff. From May 2012 through August 2013, DRMC had one full-time Cardiologist on active staff at the hospital. In August 2013, a second full-time Cardiologist joined the active staff at DRMC. DRMC anticipates performing volumes at a level that exceeds the state's minimum threshold in 2014 with the additional Cardiology coverage.

Across the country, it is become increasingly difficult for providers, without therapeutic cardiac catheterization capabilities, to attract and retain invasive and/or interventional Cardiologists. This is part of the reason that a number of providers without these capabilities are experiencing an erosion of volumes. In an effort to ensure the continued viability of the cardiac catheterization lab and the cardiology program at DRMC, it is important that the hospital is allowed to expand its cardiac catheterization program to include therapeutic capabilities.

Five Principles for Achieving Better Health (Tennessee State Health Plan).

Through the approval of this application, DRMC will be in a better position to advance the aim of the “Five Principles for Achieving Better Health” that was developed by the Division of Health Planning in Tennessee. A description of how DRMC will address each of these five principles is included below:

1. The purpose of the State Health Plan is to improve the health of Tennesseans.

RESPONSE: Through approval of this application, DRMC would be able to better provide for the health care needs of Tennesseans. As described in the previous sections of this application, heart disease incidence and mortality rates are relatively high in the state of Tennessee, but alarmingly so in the area that DRMC serves. A number of factors may contribute to this situation, but one of which relates to patients’ access to care. Of the seven Counties in the DRMC service area, six are located in Tennessee. Currently, patients need to travel outside of this six County area for a therapeutic cardiac catheterization procedures. With approval of this application, DRMC would be in a position to offer this level of care closer to home, thus improving access, eliminating or reducing the travel burden on area patients and their families, and significantly reducing the need and related costs for emergent air and ground transport.

2. Every citizen should have reasonable access to care.

RESPONSE: As previously mentioned, there are no providers in the seven-county area that DRMC serves with therapeutic cardiac catheterization capabilities. This procedure has been proven to be safely offered in hospitals without surgery on-site, which is reflected in the latest American College of Cardiology guidelines and in the state of Tennessee’s changes in regulation. Without a provider with these capabilities in the service area, patients and their families are forced to endure travel outside of the area for this higher level of care. Upon approval of this application, patients in the area will have access to this life saving procedure closer to home.

3. The state’s health care resources should be developed to address the needs of Tennesseans while encouraging competitive markets, economic efficiencies and the continued development of the state’s health care system.

RESPONSE: Through approval of this application, DRMC will be in a better position to care for the growing cardiovascular needs of its service area population. With significant growth in the 65 and older age cohort, the demand for cardiovascular services is expected to grow. Thus, contributing to a service area with a high incidence and high mortality rates associated with heart disease. An expansion in capabilities to include therapeutic cardiac catheterization at DRMC will dramatically reduce the number of necessary emergent ground and air transports, thus reducing the cost of care in the health care system.

4. Every citizen should have the confidence that the quality of health care is continually monitored and standards are adhered to by health care providers.

RESPONSE: As a new therapeutic cardiac catheterization program, it will be very important that DRMC closely monitors the clinical quality of this new service. The applicant is prepared

for this undertaking, and is committed to also benchmarking itself with hospitals across the country clinical and quality outcomes through participation in the American College of Cardiology's National Cardiovascular Data Registry CathPCI registry. DRMC will agree and cooperate with all efforts related to quality enhancements as sponsored by the State of Tennessee. These efforts will ensure DRMC is providing consistent, high-quality care to its patient population.

5. The state should support the development, recruitment and retention of a sufficient and quality health care workforce.

RESPONSE: Through approval of this application, DRMC will be in a position to offer new career opportunities to physicians and staff required to support a therapeutic cardiac catheterization program at the hospital. Additionally, through an expansion to its current catheterization capabilities, DRMC will be in a better position to recruit and retain consistent Cardiology coverage.

[END OF RESPONSES TO STANDARDS AND CRITERIA IN TENNESSEE STATE HEALTH PLAN]

b) Applications that include a Change of Site for a health care institution, provide a response to General Criterion and Standards (4)(a-c)

RESPONSE: Not Applicable (N/A). DRMC is not applying for a Change of Site approval.

2. Describe the relationship of this project to the applicant facility's long-range development plans, if any.

RESPONSE: The ability to provide therapeutic catheterization capabilities is essential to the mission of DRMC. The advancement to offer PCI would be a logical expansion of the cardiac services offered to patients by DRMC today. The inability to provide this necessary service has the potential to further erode the diagnostic catheterization volumes at DRMC, thus impacting the long-term viability of DRMC as a full-service hospital. Without approval to proceed, DRMC would be hampered in its ability to provide the standard of care to the communities it serves.

3. Identify the proposed service area and justify the reasonableness of that proposed area. Submit a county level map including the State of Tennessee clearly marked to reflect the service area. Please submit the map on 8 1/2" x 11" sheet of white paper marked only with ink detectable by a standard photocopier (i.e., no highlighters, pencils, etc.).

RESPONSE: The proposed service area includes Crockett, Dyer, Gibson, Lake, Lauderdale, and Obion counties in Tennessee and Pemiscot County in Missouri. DRMC is located in Dyer County, TN, which is situated roughly in the center of this service area. The area that defines the service area for cardiac services at DRMC is illustrated in the map in Attachment C (III) Proposed Service Area Map.

The proposed service area is defined as the area representing the location of existing and potential cardiac patients to DRMC. To determine this area, DRMC reviewed its historical discharge data, population density, and geography. Approximately 97% of DRMC's total patient volume resides in the proposed service area. Although DRMC cares for patients residing outside of this proposed

service area, this amount accounts for less than 3% of DRMC's total inpatient discharges in 2013. Therefore, DRMC is confident that the proposed service area is representative of its market for therapeutic cardiac catheterization patients in this proposal.

4. A. Describe the demographics of the population to be served by this proposal.

RESPONSE: DRMC's service area population is projected to grow by 1% over the next 5 years. This growth is supported by significant growth in the 65 and older age cohort. Based on resident population projections developed by the Tennessee State Data Center, DRMC's service area population ages 19 and over (adult population) is expected to reach more than 143,000 by 2018, an increase of 2%.

The population in the 65 and older age cohort in DRMC's service area is growing considerably and accounts for a substantial portion of the total population. As displayed in Table 11, DRMC's service area population in this age cohort is expected to grow by approximately 12 percent over the next five years, which will account for all of the growth of the adult population during that time period. In addition, this segment of the population are expected to account for more than 17% of DRMC's service area population in 2014. People aged 65 and over are at greater risk for cardiovascular disease compared to the younger population, and thus the demand for advanced cardiac services is greater in this age cohort. This elderly population is typically averse to travel long distances for care, which may be due to their increased need to engage family member assistance to make the trip. Traveling outside of their community for cardiac care that can be provided safely closer to home is a hardship this population should not have to endure. Adding PCI services at DRMC will alleviate this travel hardship for patients and their families.

Table 11 – Dyersburg Regional Medical Center Proposed Service Area Population 2013-2018¹⁵

Dyersburg Regional Medical Center Proposed Service Area Population							
Population	2013	2014	2015	2016	2017	2018	% Change 2013-2018
Age <19	50,096	49,899	49,719	49,571	49,439	49,410	-1%
Age 19-44	58,321	58,374	58,302	58,014	57,895	57,911	-1%
Age 45-64	50,644	50,446	50,494	50,667	50,675	50,478	0%
Age 65+	31,124	31,965	32,658	33,379	34,107	34,772	12%
Total	190,186	190,684	191,173	191,630	192,116	192,570	1%
Population % of Total	2013	2014	2015	2016	2017	2018	
Age <19	26%	26%	26%	26%	26%	26%	
Age 19-64	31%	31%	30%	30%	30%	30%	
Age 45-64	27%	26%	26%	26%	26%	26%	
Age 65+	16%	17%	17%	17%	18%	18%	
Total	100%	100%	100%	100%	100%	100%	

¹⁵ Data Source: Tennessee State Data Center (August 2013) and U.S. Census Bureau

B. Describe the special needs of the service area population, including health disparities, the accessibility to consumers, particularly the elderly, women, racial and ethnic minorities, and low-income groups. Document how the business plans of the facility will take into consideration the special needs of the service area population.

RESPONSE: The population in DRMC's proposed service area is not only older, but in a lower income bracket, on average when compared to the majority of Tennessee citizens, as evidenced by a high unemployment rate, a relatively low median income, and a relatively high percentage of Medicaid patients seeking care at DRMC. In 2013, DRMC's payor mix included 22% of patients covered by Medicaid. Additionally, as previously referenced residents in the service area suffer from some of the highest heart disease and heart attack mortality rates in the country. These determinants of health significantly impact access to care, as service area residents are challenged by high rates of heart disease, in a largely elderly population, that has a relatively low income when compared to other regions in Tennessee. Table 12 below portrays service area County demographics as compared to the state and nation.

Table 12 – Demographics, Dyersburg Regional Medical Center Proposed Service Area 2011, Tennessee, Missouri, USA 2010¹⁶

Population Living in Poverty, All Ages							
Area	County	Percentage	Rank in State (TN,MO)	Rank in USA	Unemployment Rate (%)	Median Income	High School Graduate (%)
Service Area	Crockett	20.0%	45	897	9.0%	\$35,370	73.4%
	Dyer	19.4%	53	1006	7.0%	\$36,121	72.9%
	Gibson	18.8%	60	1103	9.5%	\$34,050	74.5%
	Lake	43.7%	1	6	12.2%	\$23,441	61.4%
	Lauderdale	30.7%	4	124	12.1%	\$31,667	67.4%
	Obion	18.3%	67	1215	6.7%	\$37,581	76.2%
	Pemiscot, MO	30.1%	2	131	10.2%	\$26,647	N/A
State & U.S	State of TN	17.9%	N/A	N/A	7.9%	\$42,943	82.0%
	State of MO	16.2%	N/A	N/A	6.8%	\$47,202	86.8%
	United States	15.9%	N/A	N/A	7.3%	\$52,762	85.4%

DRMC's service area includes some of the poorest counties in Tennessee and Missouri. Out of the ninety-five Counties in Tennessee, Lake County ranks first in percent of people living in poverty at 43.7%, and Lauderdale County ranks fourth at 30.7%. Additionally, Pemiscot County in Missouri ranks second in Missouri counties with 30% of residents living in poverty. All counties in DRMC's proposed service area have higher percentages of the population living in poverty than the state of

¹⁶ Data Sources: for Tennessee & Tennessee Counties: Chronic Health Profile Regions and Counties: Tennessee, TN Department of Health Office of Policy, Planning & Assessment Surveillance, Epidemiology and Evaluation (December 2011); for Pemiscot, MO, State of MO, and U.S. rates: U.S. Census Bureau via CDC, 2010

TN, the state of MO, and the U.S. Congruently, all counties in the service area have a lower median income than TN, MO, and the U.S., and all DRMC service area counties have populations with lower percentages with high school graduates than the state and U.S.

The median household income for residents of Lake County is only \$23,441, which is the second lowest median income for counties in Tennessee. Likewise, Pemiscot County has the second lowest median household income for counties in Missouri at only \$26,647 annually. All counties in the proposed service area are lower than the \$42,943 Tennessee annual median household income. The low income, coupled with high unemployment rates places residents in challenging situations, particularly when they are being told to travel roughly an hour away from home to receive advanced cardiac services that can safely be offered close to home.

DRMC is proposing to offer diagnostic and therapeutic cardiac cath services in medically underserved areas (MUAs) as designated by the Health Resources and Services Administration (HRSA). As of January 2014, all counties within DRMC's proposed service area – Crockett-TN, Dyer-TN, Lake-TN, Lauderdale-TN, Obion-TN, and Pemiscot-MO Counties – are designated MUAs, “which are areas or populations designated by HRSA as having: too few primary care providers, high infant mortality, high poverty and/or high elderly population.”¹⁷ This further emphasizes the need for advanced cardiovascular care services for residents in the areas surrounding DRMC.

With almost 43,000 deaths, heart disease is the leading cause of death in Tennessee¹⁸. The population living in the proposed service area experiences prevalence and mortality of heart disease that is substantially higher than the State of Tennessee and national averages. In fact, the counties in DRMC's proposed service area rank in the highest quartile of heart disease mortality in the state of Tennessee, and all of the service area counties have higher heart disease mortality rates than Tennessee and the United States. In DRMC's proposed service area, Crockett County ranks first in Heart Disease Mortality out of all 95 Tennessee Counties with a mortality rate of 395.8 per 100,000 people¹⁹. Pemiscot County, Missouri has the second highest mortality rate in DRMC's proposed service area with a rate of 326.9 per 100,000 people. The remaining DRMC service area counties have heart disease mortality rates above 250 per 100,000 people, which are higher than the state of Tennessee, Missouri, and the United States mortality rates. Furthermore, the hospitalization rate of residents in all counties but one is higher than the state of Tennessee. Table 13 below depicts the heart disease death rates, rankings, and hospitalization in the proposed service area, Tennessee, Missouri, and the United States, and Table 14 depicts AMI mortality rates and rankings in the proposed service area, Tennessee, Missouri, and the United States.

¹⁷ “Find Shortage Areas: MUA/P by State and County,” Health Resources and Services Administration, <http://muafind.hrsa.gov/index.aspx>, Accessed 23 January 2014.

¹⁸ Data Source: TN DH Statistics 2007-2009

¹⁹ Data Source: TN DH Office of Policy, Planning & Assessment Surveillance, Epidemiology, and Evaluation, Dec 2011

Table 13 – Heart Disease Mortality Rates, Rankings, and Hospitalization, Dyersburg Regional Medical Center Proposed Service Area, Tennessee (2011), Missouri, USA 2008-2010²⁰

Heart Disease							
Area	County	Mortality - All Ages	Mortality Ranking (1 = <i>highest</i>) in State (TN) - All Ages Total Counties TN=94, MO=115	Mortality - Ages 35+	Mortality Ranking (1 = <i>highest</i>) in State - Ages 35+ Total Counties TN=94, MO=115	Mortality Ranking (1 = <i>highest</i>) in USA - Ages 35+	Hospitalization
Proposed Service Area	Crockett, TN	395.8	1	706.7	1	13	1,631.1
	Dyer, TN	250.4	35	550.3	9	155	2,146.2
	Gibson, TN	245.3	38	503.9	24	318	1,572.3
	Lake, TN	262.8	25	534.1	15	207	2,762.6
	Lauderdale, TN	279.4	15	537.8	13	144	1,827.8
	Obion, TN	253.6	33	509.2	20	291	1,305.3
	Pemiscot, MO	326.9	N/A	618.6	6	42	N/A
State & U.S	State of TN	220.7	N/A	426.5	N/A	9	1,306.8
	State of MO	209.1	N/A	405.4	N/A	13	N/A
	United States	190.6	N/A	358.6	N/A	N/A	N/A

Table 14 – AMI Mortality Rates& Rankings, Dyersburg Regional Medical Center Proposed Service Area, Tennessee (2011), Missouri, USA 2008-2010²¹

AMI (Acute Myocardial Infarction) – Heart Attack				
Area	County	Mortality - Ages 35+	Mortality Ranking (1 = <i>highest</i>) in State - Ages 35+ Total Counties TN=94, MO=115	Mortality Ranking (1 = <i>highest</i>) in USA - Ages 35+
Proposed Service Area	Crockett, TN	201.0	17	151
	Dyer, TN	160.8	36	444
	Gibson, TN	164.1	30	405
	Lake, TN	162.5	33	848
	Lauderdale, TN	156.8	43	480
	Obion, TN	249.7	10	70
	Pemiscot, MO	365.3	114	14
State & U.S	State of TN	119.9	N/A	6
	State of MO	120.0	N/A	5

²⁰ Data Sources: for Mortality All Ages and Hospitalization: Chronic Health Profile Regions and Counties: Tennessee, TN Department of Health Office of Policy, Planning & Assessment Surveillance, Epidemiology and Evaluation; for Mortality Ages 35+: National Vital Statistics System from National Center for Health Statistics via CDC

²¹ Data Source: National Vital Statistics System from National Center for Health Statistics via CDC

	United States	75.7	N/A	N/A
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With some of the highest heart disease and AMI mortality rates in the country, residents in DRMC's proposed service area are in great need for access to advanced cardiovascular care. Since "time is muscle," and delayed treatment equates to greater risk for permanent irreversible damage to heart muscle, it is paramount that DRMC's proposed service area population have access to treatment as quickly as possible. The excerpt below from "The Case for Community Hospital Angioplasty" illustrates this fact in more detail:

"The mortality benefit of primary PCI decreases as the time delay to PCI increases, and this benefit may disappear when the delay to PCI is more than 1 hour compared with the time to administration of a fibrinolytic agent. Patients in the United States who are transferred for primary PCI are treated 71 minutes later than patients who receive primary PCI locally (171 versus 100 minutes), according to data from the NRM [National Registry of Myocardial Infarction]. This same NRM registry demonstrates that a door-to-balloon time of 2.5 to 3 hours, as seen in patients transferred for PCI, is associated with a 60% increase in risk-adjusted mortality compared with <2 hours from door to balloon time."²²

If DRMC were to add PCI services, all residents living in DRMC's proposed service area would have access to PCI services in less than a 1 hour drive, and most would be able to get to DRMC in less than 20-30 minutes.²³ Table 15 below depicts the distance between DRMC and the two closest providers with PCI capabilities.

Table 15 – Distance and Travel time from Dyersburg Regional Medical Center to Nearest PCI Centers & Cardiac Services Available²⁴

Hospital Name	Address	Miles from Dyersburg Regional Medical Center	Driving Time from Dyersburg Regional Medical Center	Major Roads	Cardiac Services Available		
					Open Heart Surgery	Diagnostic Cath	Therapeutic Cath
<i>Dyersburg Regional Medical Center</i>	<i>400 East Tickle Street, Dyersburg, TN 38024</i>	<i>N/A</i>	<i>N/A</i>	<i>N/A</i>	<i>No</i>	<i>Yes</i>	<i>No</i>
Regional Hospital of Jackson	367 Hospital Boulevard Jackson, TN 38305	47.8 miles	51 minutes	US-412 E	No	Yes	Yes
Jackson-Madison County General Hospital	620 Skyline Drive Jackson, TN 38301	48.4 miles	55 minutes	TN-20 E	Yes	Yes	Yes

²² Reference: Wharton, Thomas P., "The Case for Community Hospital Angioplasty," *Circulation*. 2005; 112: 3509-3534.

²³ Data Source: Google Maps

²⁴ Data Source: Google Maps, 2012 Tennessee Joint Annual Report

Emergency Medical Service (EMS) providers are able to shorten access times using ambulances and, in some cases, air transport. However, the cost of EMS transport to patients is significant and adds to the overall cost of care for patients, as shown in Table 16. It cannot be understated that across the country many EMS providers have taken a more active role in the facilitation of triaging and critically managing chest pain patients. Their direct involvement in the care and management of this patient population has become a driving force as many states are recognizing and addressing the need for these providers to transport these patients to the closest STEMI center.

Table 16 – EMS Ground and Air Transport Distance and Costs²⁵

Hospital Name	Address	Ground Miles from Dyersburg Regional Medical Center	Ground Transfer Cost	Approximate Nautical Miles from Dyersburg Regional Medical Center	Air Transfer Cost
Regional Hospital of Jackson	367 Hospital Boulevard Jackson, TN 38305	47.8 miles	\$1,657	38.8 miles	\$30,513
Jackson-Madison County General Hospital	620 Skyline Drive Jackson, TN 38301	48.4 miles	\$1,666	41.9 miles	\$31,775

DRMC will remain focused on improving access to care for the poor, elderly, women, and racial and ethnic minorities. In DRMC's proposed service area, the elderly population (over age 65) is expected to increase by 12 percent in the next five years, indicating an increased need for cardiovascular-related services given that people aged 65 and over have higher risk of cardiovascular disease. Additionally, DRMC's proposed service area has a large percentage of families with female heads of household, as compared to the rest of Tennessee and Missouri. Women are clinically misdiagnosed for cardiovascular disease, particularly when they are experiencing a heart attack, and more attention should be paid to properly diagnosing women. Given the fact that heart disease remains the number one cause of death for women in the United States, DRMC intends to become actively involved in the pursuit of educating the community, and will specifically utilize the tools provided by the American Heart Association "Go Red For Women" campaign; thus increasing awareness through education and treatment options specific to the female population.

The applicant's plan to expand services by purchasing requisite equipment adequate to provide therapeutic catheterization services will serve the local community in Dyer County and the surrounding counties as the population becomes increasingly older and experiences more health problems. A local and easily accessible cardiac catheterization laboratory that not only provides critical diagnostic services but also has the capability to intervene when necessary will be a vital asset to the northwest Tennessee community.

- 5. Describe the existing or certified services, including approved but unimplemented CONs, of similar institutions in the service area. Include utilization and/or occupancy trends for each of the most recent three years of data available for this type of project. Be certain to list each institution and**

²⁵ Data Sources: Source: Costs & Ground Miles provided by EMS Representative in Dyersburg, TN; for Nautical Miles: Daft Logic Version 5.7 (22/01/2014), <http://www.daftlogic.com/>

its utilization and/or occupancy individually. Inpatient bed projects must include the following data: admissions or discharges, patient days, and occupancy. Other projects should use the most appropriate measures, e.g., cases, procedures, visits, admissions, etc.

RESPONSE: There are currently no existing or certified PCI centers in DRMC's proposed service area. The nearest PCI centers, Regional Hospital of Jackson and Jackson-Madison County General, are located outside of the proposed service area in Madison County. DRMC did not discharge any patients originating from Madison County in 2013, which is why it is not considered part of hospital's service area. Utilization trends for hospitals located within the DRMC service area are listed in Table 17 below.

Of the seven hospitals in DRMC's service area, none have PCI capabilities today. Therefore, it can be safely assumed that DRMC would not impact any of the other six hospitals in the service area with an expansion to offer PCI services.

Table 17 – Cardiac Utilization Trends 2010-2012, Dyersburg Regional Medical Center Proposed Service Area²⁶

Hospitals in Dyersburg Regional Medical Center's Proposed Service Area	Cardiac Utilization Trends (volume of patients)		
	2010	2011	2012
Baptist - Lauderdale	0	0	0
Diagnostic Cardiac Catheterization ("Cath")	0	0	0
Percutaneous Transluminal Coronary Angioplasty ("PTCA")	0	0	0
Stents	0	0	0
Baptist - Union City	108	37	31
Cath	54	37	31
PTCA	0	0	0
Stents	0	0	0
Dyersburg Regional Medical Center	376	326	275
Cath	376	326	275
PTCA	0	0	0
Stents	0	0	0
Gibson General Hospital	0	0	0
Cath	0	0	0
PTCA	0	0	0
Stents	0	0	0
Humboldt General Hospital	0	0	0
Cath	0	0	0
PTCA	0	0	0

²⁶ Data Sources: Tennessee Department of Health, Joint Annual Report of Hospitals 2010-2012; DRMC internal discharge data for DRMC volume to reflect patients rather than procedures

Stents	0	0	0
Milan General Hospital	0	0	0
Cath	0	0	0
PTCA	0	0	0
Stents	0	0	0
Grand Total	1,176	2,376	303

6. Provide applicable utilization and/or occupancy statistics for your institution for each of the past three (3) years and the projected annual utilization for each of the two (2) years following completion of the project. Additionally, provide the details regarding the methodology used to project utilization. The methodology must include detailed calculations or documentation from referral sources, and identification of all assumptions.

RESPONSE: The applicant anticipated utilizing two approaches to project the volume of patients for an expansion to offer PCI services. The first approach would entail evaluating transfer data to understand the number of patients that are being transferred from DRMC and those that are leaving the service area without stopping at DRMC to access a higher level of cardiac care that is not currently offered at the hospital. This approach is incorporates patient preferences in terms of the hospital that is primarily utilized for care, and is indicative of referral (self and physician) patterns in the region. The second approach would entail evaluating all payor, patient discharge data by patient origin to understand the utilization of services and market share/volume by providers in the area. Through several interactions with Tennessee Department of Health, it is clear that all payor patient discharge data by patient origin and procedural utilization statistics by age cohort in the service area and the state are not currently available. Due to the inability to access this data, DRMC was not able to conduct the second approach to volume projections.

To project patient volumes for an expansion to offer PCI at DRMC, the applicant analyzed patient transfer data from the hospital records and that of EMS ground and air transfer providers in Dyersburg, Tennessee. The ground transport EMS provider, Dyersburg Regional Emergency Medical Services, services patients in the Dyer County market, whereas the air transport provider is based in Dyersburg, Tennessee and services a 60-mile radius surrounding their location.

Through an evaluation of this transfer data, it is clear that over 1,000 patients left DRMC for cardiovascular care in 2013, with an average of over 900 such transfers per year for the past 3 years. The primary reason that patients would be transferred from DRMC to other facilities for cardiac care is the lack of current capabilities at the hospital. As it relates to cardiac services, PCI and open heart surgery capabilities represent the significant gaps in the current services offered. The volume of ground and air transfers from DRMC for cardiac reasons for the previous three years can be found in Table 18 below.

Table 18 – Volume of Ground and Air Transfers for Cardiac Reasons from DRMC

Mode of Transfer	2011	2012	2013*
EMS Ground Transfer	777	935	1,018
EMS Air Transfer	(not available)	2	3
Total Transfers	777**	937	1,021

*EMS Ground Transfer data was annualized for 2 months, and EMS Air Transfer data for 3 months for 2013.

**Total volume of transfers in 2011 is not reflective of EMS Air Transfer volume as it was not available.

In addition to the volume of transfers from DRMC, there are also patients that EMS providers transfer from the area without first stopping at DRMC. This may be due to the patient's history, condition, and/or preference. If an EMS provider suspects a patient is having a heart attack, the provider will bypass DRMC and bring the patient to the nearest hospital that offers PCI services. Upon approval to expand services at DRMC to offer PCI, EMS providers would not need to drive by DRMC if it were the nearest hospital as it would then be able to provide the recognized standard of care to patients experiencing an AML. Table 19 below displays the volume of patients transported from Dyer County to providers outside of the DRMC service area for cardiac care.

Table 19 – Volume of Patients Transported via EMS from Dyer County for Cardiac Reasons without Receiving Care at DRMC

Mode of Transport	2011	2012	2013*
EMS Ground Transport	102	132	170
EMS Air Transport	(not available)	47	44
Total Transports	102**	179	214

*EMS Ground Transfer data was annualized for 2 months, and EMS Air Transfer data for 3 months for 2013.

**Total volume of transports in 2011 is not reflective of EMS Air Transfer volume as it was not available.

It is unclear what services were provided to each of the patients that were transferred in the data above. However, it is reasonable to assume that these patients were transferred to receive a higher level of cardiac care not available at DRMC (e.g., open heart surgery, coronary angioplasty), were deemed too high-risk for DRMC, and/or were managed medically at the receiving hospital. As a conservative approach to this transfer volume, DRMC assumed that just 25% of this patient population received a therapeutic catheterization procedure. Using this assumption, 309 patients transferred from DRMC or Dyer County via EMS providers would have had a PCI procedure performed in 2013. This total does not include the volume of patients that would have received a elective PCI procedure as an outpatient. As is the case with a number of other procedure types, PCI patients receiving PCI procedures continue to migrate to an outpatient setting for their care. Although the rate of inpatient to outpatient PCIs can be 70%/30% respectively, DRMC projected a more conservative estimate of 80%/20% for these volume projections. If we assume that the 309 patients is representative of the 80% complement, then the total inpatient and outpatient PCI patients would total 386 for 2013. With roughly 95% of cardiac interventions occurring in the above 45 age cohort, it can be assumed that 367 of the 386 PCI patients were in this age cohort. It is important to note that this projection does not include patients that reside in other service area Counties that bypassed DRMC as well, due to the EMS transfer data not being available. For this and other reasons, 386 PCIs is deemed to be a conservative estimate of the market volumes in the DRMC service area.

When evaluating the validity of these volume projections, DRMC compared the utilization rate based on these calculations in the service area to that of the country. Table 20 below provides a comparison of utilization rates within the DRMC service area to the nation.

Table 20 – 2013 PCI Utilization Rates in DRMC Service Area and the Nation

2013 Service Area Population	190,186
2013 Estimated PCI Procedures in DRMC Service Area	386
Service Area Utilization Rate for PCI (per 1,000 population)	2.03
National Utilization Rate for PCI* (per 1,000 population)	2.80

*Represents a calculated utilization rate based upon 2011 discharge data derived from AHRO HCUPNet; Population sourced from U.S. Census data for 2011.

As can be seen from Table 20 above, this approach to projecting PCI volumes is considered reasonable and conservative. Although DRMC anticipates positively impacting the relatively low utilization rates for PCI, the volume projection methodology for a new program at DRMC did not incorporate a growth in the calculated utilization rate. Rather, the rate of 2.03 PCI per 1,000 of the population was applied to the population projections for the area to determine the market potential for a PCI program at DRMC. Therefore, any growth in market potential is based directly on the projected changes in the service area population.

When projecting potential PCI patient volumes, DRMC its ability to attract patients for PCI services would grow over time. Although the vast majority of patients transferred from the area are seeking care at DRMC first, the hospital assumes that it will need to develop a reputation for this new service over time. Therefore, DRMC assumed it would capture one-third of the projected market potential in its first year of operation, growing to one half of the potential by the third year of operation. Details of this volume projection methodology can be found in Table 21 below.

Table 21 – DRMC PCI Volume Projections

	2013		Year 1 (2015)	Year 2 (2016)	Year 3 (2017)
PCI Volume in DRMC Service Area	386		392	395	398
Projected DRMC Market Share	0%		33%	42%	50%
DRMC PCI Volume	0		131	165	199

Historic volume statistics for DRMC are derived from the hospital's internal financial systems, and are case-based (i.e., the volume represent number of patients) rather than procedure-based. Therefore, the projected volumes for diagnostic cardiac catheterization are not double-counted in the projected PCI patient volumes.

Table 22 below displays the applicant's volume statistics and subsequent impact on lab utilization for the past three years with the projected volumes and annual utilization for each of the first two years following the initiation of therapeutic catheterization services at DRMC.

Table 22 – DRMC's Historic and Projected Cardiac Catheterization Volumes and Lab Utilization

Dyersburg Regional Medical Center Utilization Statistics	HISTORIC			PROJECTED	
Service	2011	2012	2013	Year 1	Year 2
Diagnostic Cardiac Cath	343	294	218	393	494
Therapeutic Cardiac Cath	0	0	0	131	165
Total Adult Cardiac Cath Lab Cases	343	294	218	524	659
DRMC Cardiac Cath Labs	1	1	1	1	1
Volume of Weighted Cases Available (2,000 per lab)	2,000	2,000	2,000	2,000	2,000
DRMC Weighted Cases	343	294	218	655	824
Lab Utilization	17.2%	14.7%	10.9%	32.8%	41.2%

* The decline in volume in 2012 and 2013 was due to the departure of a Cardiologist from the medical staff. From May 2012 through August 2013, DRMC had one full-time Cardiologist on active staff at the hospital. In August 2013, a second full-time Cardiologist joined the active staff at DRMC. DRMC anticipates performing volumes at a level that exceeds the state's minimum threshold in 2014 with the additional Cardiology coverage.

Across the country, it is become increasingly difficult for providers, without therapeutic cardiac catheterization capabilities, to attract and retain invasive and/or interventional Cardiologists. This is part of the reason that a number of providers without these capabilities are experiencing an erosion of volumes. In an effort to ensure the continued viability of the cardiac catheterization lab and the Cardiology program at DRMC, it is important that the hospital is allowed to expand its cardiac catheterization program to include therapeutic capabilities.

When analyzing the market potential for PCI services in the DRMC service area, it is clear that the applicant will exceed the minimum volume thresholds of 400 diagnostic/therapeutic cardiac catheterizations with at least 75 being therapeutic within the 1st year of operation with the initiation of a PCI program. For this reason, DRMC meets the market demand requirements for an expansion in capabilities to offer PCI in its service area.

ECONOMIC FEASIBILITY

1. Provide the cost of the project by completing the Project Costs Chart on the following page. Justify the cost of the project.
 - All projects should have a project cost of at least \$3,000 on Line F. (Minimum CON Filing Fee). CON filing fee should be calculated from Line D. (See Application Instructions for Filing Fee)
 - The cost of any lease (building, land, and/or equipment) should be based on fair market value or the total amount of the lease payments over the initial term of the lease, whichever is greater. Note: This applies to all equipment leases including by procedure or "per click" arrangements. The methodology used to determine the total lease cost for a "per click" arrangement must include, at a minimum, the projected procedures, the "per click" rate and the term of the lease.

- The cost for fixed and moveable equipment includes, but is not necessarily limited to, maintenance agreements covering the expected useful life of the equipment; federal, state, and local taxes and other government assessments; and installation charges, excluding capital expenditures for physical plant renovation or in-wall shielding, which should be included under construction costs or incorporated in a facility lease.
- For projects that include new construction, modification, and/or renovation; documentation must be provided from a contractor and/or architect that support the estimated construction costs.

RESPONSE: The costs for the project are set forth on the Project Cost Chart. The costs for this project are considered reasonable and relatively low due to DRMC already having a cardiac catheterization lab in place with diagnostic capabilities. DRMC will purchase the requisite equipment to advance its capabilities to offer PCI services.

Project Costs Chart	
A. Construction and Equipment acquired by purchase	Cost
1. Architectural and Engineering Fees	\$0.00
2. Legal, Administrative (Excluding CON Filing Fee), Consultant Fees	\$147,000.00
3. Acquisition of Site	\$0.00
4. Preparation of Site	\$0.00
5. Construction Costs	\$0.00
6. Contingency Fund	\$17,763.00
7. Fixed Equipment (not included in construction costs)	\$100,000.00
8. Moveable Equipment (Combined IVUS & FFR System)	\$100,000.00
9. Other (Specify) _____	\$0.00
B. Acquisition by gift, donation, or lease	
1. Facility (inclusive of building and land)	\$0.00
2. Building only	\$0.00
3. Land only	\$0.00
4. Equipment (Specify)	\$0.00
5. Other (Specify) _____	\$0.00
C. Financing Costs and Fees	
1. Interim Financing	\$0.00
2. Underwriting Costs	\$0.00
3. Reserve for One Year's Debt Service	\$0.00
4. Other (Specify)	\$0.00
D. Estimated Project Cost (A + B + C)	\$364,763.00
E. CON Filing Fee	\$3,000.00
F. Total Estimated Project Cost (D + E)	\$367,763.00
TOTAL	367,763.00

2. Identify the funding sources for this project.

Please check the applicable item(s) below and briefly summarize how the project will be financed. *(Documentation for the type of funding MUST be inserted at the end of the application, in the correct alpha/numeric order and identified as Attachment C, Economic Feasibility-2.)*

- ☐ A. Commercial loan--Letter from lending institution or guarantor stating favorable initial contact, proposed loan amount, expected interest rates, anticipated term of the loan, and any restrictions or conditions;
- ☐ B. Tax-exempt bonds--Copy of preliminary resolution or a letter from the issuing authority stating favorable initial contact and a conditional agreement from an underwriter or investment banker to proceed with the issuance;
- ☐ C. General obligation bonds—Copy of resolution from issuing authority or minutes from the appropriate meeting.
- ☐ D. Grants--Notification of intent form for grant application or notice of grant award; or
- ☒ E. Cash Reserves--Appropriate documentation from Chief Financial Officer.
- ☐ F. Other—Identify and document funding from all other sources.

RESPONSE: See the attached letter from the applicant's Chief Financial Officer in Attachment C2, Economic Feasibility -2 Funding Letter.

3. Discuss and document the reasonableness of the proposed project costs. If applicable, compare the cost per square foot of construction to similar projects recently approved by the Health Services and Development Agency.

RESPONSE: DRMC currently offers diagnostic catheterization services, and is proposing an expansion to service capabilities to include therapeutic catheterization services. In order to offer therapeutic catheterization services, DRMC is anticipating an investment of \$200,000 into equipment that includes an intravascular ultrasound imaging and fractional flow reserve software, and an uninterrupted power supply for the cardiac catheterization lab to ensure the power supply is not interrupted by a power failure. Additionally, DRMC anticipates spending an additional \$164,763 for legal fees, consultant fees, and program implementation support from now until the end of its first year of operation. Thus, the total estimated project cost is \$364,763 (excluding CON filing fee). This total investment is considered reasonable, as DRMC does not have to invest in additions or renovations to its existing facility or into new imaging equipment.

4. Complete Historical and Projected Data Charts on the following two pages--Do not modify the Charts provided or submit Chart substitutions! Historical Data Chart represents revenue and expense information for the last three (3) years for which complete data is available for the institution. Projected Data Chart requests information for the two (2) years following the completion of this proposal. Projected Data Chart should reflect revenue and expense projections

for the Proposal Only (i.e., if the application is for additional beds, include anticipated revenue from the proposed beds only, not from all beds in the facility).

RESPONSE: See Historical and Projected Data Charts in the following pages.

HISTORICAL DATA CHART

SUPPLEMENTAL

Give information for the last three (3) years for which complete data are available for the facility or agency.

	Year: 2011	Year: 2012	Year: 2013
A. Utilization/Occupancy Data	13,109	12,615	11,033
B. Revenue from Services to Patients			
1. Inpatient Services	\$177,313,194	\$161,453,832	\$152,247,675
2. Outpatient Services	\$221,867,035	\$243,735,249	\$242,478,289
3. Emergency Services	\$39,556,905	\$48,242,459	\$53,582,570
4. Other Operating Revenue	\$522,408	\$398,483	\$351,637
Specify: See Attachment			
Gross Operating Revenue	\$439,259,542	\$453,830,023	\$448,660,171
C. Deductions from Operating Revenue			
1. Contract Deductions	\$361,201,645	\$377,656,922	\$377,527,536
2. Provision for Charity Care	\$2,143,445	\$2,658,744	\$1,578,834
3. Provision for Bad Debt	\$11,504,494	\$12,376,445	\$10,912,316
Total Deductions	\$374,849,584	\$392,692,111	\$390,018,686
NET OPERATING REVENUE	\$64,409,958	\$61,137,912	\$58,641,485
D. Operating Expenses			
1. Salaries and Wages	\$26,387,727	\$24,305,121	\$22,934,196
2. Physicians' Salaries and Wages	\$0	\$0	\$0
3. Supplies	\$7,436,910	\$6,977,615	\$6,340,693
4. Taxes	\$5,017,623	\$5,496,546	\$5,425,912
5. Depreciation	\$4,787,333	\$5,338,108	\$3,573,482
6. Rent	\$1,395,588	\$1,460,407	\$1,411,496
7. Interest, other than Capital	\$0	\$0	\$0
8. Management Fees:			
a. Fees to Affiliates	\$2,185,199.00	\$2,582,185.00	\$2,278,576.00
b. Fees to Non-Affiliates	\$0.00	\$0.00	\$0.00
9. Other Expenses	\$8,949,797.00	\$10,301,713.00	\$8,688,545.00
Specify: See Attached.			
Total Operating Expenses	\$56,160,177.00	\$56,461,695.00	\$50,652,900.00
E. Other Revenue (Expenses)--Net	\$0.00	\$0.00	\$0.00
Specify:			
NET OPERATING INCOME (LOSS)	\$8,249,781.00	\$4,676,217.00	\$7,988,585.00
F. Capital Expenditures			
1. Retirement of Principal			
2. Interest	\$3,357,859.00	\$3,681,870.00	\$4,148,940.00
Total Capital Expenditures	\$3,357,859.00	\$3,681,870.00	\$4,148,940.00
NET OPERATING INCOME (LOSS)	\$8,249,781.00	\$4,676,217.00	\$7,988,585.00
LESS CAPITAL EXPENDITURES	\$3,357,859.00	\$3,681,870.00	\$4,148,940.00
NOI LESS CAPITAL EXPENDITURES	\$4,891,922.00	\$994,347.00	\$3,839,645.00

HISTORICAL DATA CHART ATTACHMENT

SUPPLEMENTAL

Other Operating Revenue (Line B, 4):

Cafeteria Revenue
 Vending Machine Revenue
 Medical Records copying fees
 Senior Circle Memberships
 Healthy Woman Memberships
 Rental Revenue
 Gain or Loss on Disposal of Fixed Assets
 Grant Income
 Other Misc. Revenue

OTHER EXPENSE CATEGORIES (Line D, 9)

Year: 2011

Year: 2012

Year: 2013

1. Medical Specialists Fees	\$1,914,784	\$2,018,643	\$2,130,953
2. Purchased Services	\$4,198,638	\$4,631,095	\$5,205,456
3. Physician Recruiting	\$16,696	\$52,164	\$59,546
4. Repairs	\$1,161,687	\$1,448,925	\$1,369,971
5. Marketing	\$187,027	\$125,609	\$110,927
6. Utilities	\$1,273,261	\$1,238,750	\$1,101,133
7. Other Misc. Operating Expense	\$847,245	\$786,534	\$728,434
8. HITECH Incentives	-\$649,541	-\$7	-\$2,017,875
Total Other Expenses	\$8,949,797	\$10,301,713	\$8,688,545

June 23, 2014**12:30 pm****PROJECTED DATA CHART (Replacement)**

Give information for the two (2) years following completion of this proposal. The fiscal year begins in January.

	Year 1	Year 2
A. Utilization/Occupancy Data (Incremental Patients)	306	440
B. Revenue from Services to Patients		
1. Inpatient Services	\$16,410,869	\$22,884,027
2. Outpatient Services	\$2,744,429	\$3,862,040
3. Emergency Services	\$0	\$0
4. Other Operating Revenue (Specify) _____	\$0	\$0
Gross Operating Revenue	\$19,155,298	\$26,746,067
C. Deductions from Operating Revenue		
1. Contractual Adjustments	\$16,144,396	\$22,542,019
2. Provisions for Charity Care	\$67,097	\$93,686
3. Provisions for Bad Debt	\$456,291	\$637,108
Total Deductions	\$16,667,784	\$23,272,813
NET OPERATING REVENUE	\$2,487,514	\$3,473,254
D. Operating Expenses		
1. Salaries and Wages	\$130,353	\$132,666
2. Physicians' Salaries and Wages	\$438,000	\$438,000
3. Supplies	\$574,153	\$817,829
4. Taxes	\$0	\$0
5. Depreciation	\$40,000	\$40,000
6. Rent	\$0	\$0
7. Interest, other than Capital	\$0	\$0
8. Management Fees:	\$0	\$0
a. Fees to Affiliates	\$0	\$0
b. Fees to Non-Affiliates	\$0	\$0
9. Other Expenses		
Specify: (See Attached) _____	\$93,838	\$122,737
Total Operating Expenses	\$1,276,344	\$1,551,232
E. Other Revenue (Expenses)--Net	(\$172,000)	(\$15,000)
Specify: Marketing, Legal, Implementation		
NET OPERATING INCOME (LOSS)	\$1,039,170	\$1,907,022
F. Capital Expenditures		
1. Retirement of Principal	\$0	\$0
2. Interest	\$0	\$0
Total Capital Expenditures	\$0	\$0
NET OPERATING INCOME (LOSS)	\$1,039,170	\$1,907,022
LESS CAPITAL EXPENDITURES	\$0	\$0
NOI LESS CAPITAL EXPENDITURES	\$1,039,170	\$1,907,022

June 23, 2014**12:30 pm****PROJECTED DATA CHART-OTHER EXPENSES**

Explanation Line D, 8,a: It is not practically possible to allocate a portion of the Affiliate Mangement Fees for the entire hosptial to one secific service line.

<u>OTHER EXPENSE CATEGORIES</u>	<u>Year 1</u>	<u>Year 2</u>
1. Maintenance Contracts	\$0.00	\$20,000.00
2. ACC-NCDR Database Participation Fees	\$5,625.00	\$5,625.00
3. Indirect Expenses	\$70,451.00	\$95,049.00
4. Contingency Expense	\$17,762.00	\$2,063.00
Total Other Expenses	\$93,838.00	\$122,737.00

June 23, 2014**12:30 pm**

5. Please identify the project's average gross charge, average deduction from operating revenue, and average net charge.

RESPONSE: The applicant projects the following charges for the first two years of operation:

	Year 1	Year 2
Average Gross Charge	\$62,599	\$60,786
Average Deduction from Operating Revenue	\$54,470	\$52,893
Average Net Charge	\$8,129	\$7,894

6. A. Please provide the current and proposed charge schedules for the proposal. Discuss any adjustment to current charges that will result from the implementation of the proposal. Additionally, describe the anticipated revenue from the proposed project and the impact on existing patient charges.

RESPONSE: DRMC does not currently perform PCI services, and therefore, does not have a schedule for charges for these services in its current hospital chargemaster. For this reason, DRMC worked with other hospitals in its health system to develop proposed pricing for PCI services. Proposed charges for PCI procedures by CPT code are included in Table 23 below.

Table 23 – Proposed PCI Charges by CPT Code

CPT 4 (CY14 Final OPPS)	Current Charges	Proposed Charges
92920	N/A	\$24,089.42
92921	N/A	\$19,271.54
92924	N/A	\$35,968.46
92925	N/A	\$35,968.46
92928	N/A	\$28,557.91
92929	N/A	\$28,557.91
92933	N/A	\$28,557.91
92934	N/A	\$28,557.91
92937	N/A	\$28,557.91
92938	N/A	\$28,557.91
92941	N/A	\$28,557.91
92943	N/A	\$28,557.91
92944	N/A	\$28,557.91
92978	N/A	\$924.00
92979	N/A	\$924.00
93571	N/A	\$2,958.95
93572	N/A	\$2,958.95
C9600	N/A	\$34,617.38
C9601	N/A	\$34,617.38
C9602	N/A	\$34,617.38
C9603	N/A	\$34,617.38
C9604	N/A	\$34,617.38

C9605	N/A	\$34,617.38
C9606	N/A	\$34,617.38
C9607	N/A	\$34,617.38
C9608	N/A	\$34,617.38

The charges included in Table 23 above are reflective of the anticipated charges for PCI procedures, and are not inclusive of all charges involved in the patients' care. The anticipated net operating revenue from the proposed project, including projected PCI and incremental diagnostic catheterization volumes with this expansion of services, will total \$2,610,530 in Year 1 and \$3,500,268 in Year 2. There will be no anticipated impact on existing patient charges at DRMC. Although there will be no impact on charges, the cost to patients should decrease if DRMC were to offer PCI services, since they would be able to receive a diagnostic catheterization and PCI at one location at one time, minimizing the times the patient would need to undergo a cath procedure. Additionally, the cost of emergency transport would significantly decrease with the lack of need to transport as many patients outside of the area for care. It is important to note that the percentage of patients needing an urgent transfer to surgery during a PCI procedure is less than 0.3%.²⁷

- A. Compare the proposed charges to those of similar facilities in the service area/adjoining service areas, or to proposed charges of projects recently approved by the Health Services and Development Agency. If applicable, compare the proposed charges of the project to the current Medicare allowable fee schedule by common procedure terminology (CPT) code(s).**

RESPONSE: There are no providers in DRMC's service area that offer PCI services today. Therefore, comparisons cannot be made between DRMC's proposed charges and that of other providers in the service area. However, being that DRMC is part of a health system, the applicant worked with another system hospital, the Regional Hospital of Jackson, to develop proposed charges for this service. At this time, DRMC's proposed charges for PCI services are equal to those at the Regional Hospital of Jackson. It is important to note, however, that charge data for comparative facilities is not publically available at the CPT-code level in Tennessee.

The proposed charges for these procedures are just one aspect of the cost involved in caring for patients with these conditions. Without a provider with PCI capabilities in the service area, patients are forced to leave the service area and travel significant distances to receive treatment. This travel may include traditional modes of transportation in non-urgent situations. However, for patients experiencing a heart attack, it is likely to involve air or ground transport via EMS providers. The cost related to this mode of transport can increase the cost of patient care exponentially and should be factored into the cost of care equation.

- 1. Discuss how projected utilization rates will be sufficient to maintain cost-effectiveness.**

RESPONSE: The applicant expects that this project will be cost-effective within the first two years of operation given that projected utilization rates are sufficient to generate profitability. With a limited investment required to expand DRMC's capabilities in its existing cardiac catheterization lab space, the applicant expects to achieve a positive ROI even within the first full year of operation.

²⁷ Data Source: 2011 ACC guidelines

8. Discuss how financial viability will be ensured within two years; and demonstrate the availability of sufficient cash flow until financial viability is achieved.

RESPONSE: The applicant projects financial viability will be ensured with a projected positive return on investment ("ROI") within the first full year of service. The projected net operating income for the proposed project in the first full year of operation will be \$1,125,224. Dyersburg Hospital Corporation d/b/a Dyersburg Regional Medical Center is providing funding for this project, as well as for the hospital generally. Cash flow support for the project will be provided by Community Health Systems where necessary on an interim basis.

9. Discuss the project's participation in state and federal revenue programs including a description of the extent to which Medicare, TennCare/Medicaid, and medically indigent patients will be served by the project. In addition, report the estimated dollar amount of revenue and percentage of total project revenue anticipated from each of TennCare, Medicare, or other state and federal sources for the proposal's first year of operation.

RESPONSE: DRMC currently participates in the Medicare and TennCare programs, and there are no plans to discontinue participation. DRMC cared for over 3,390 Medicaid patients (96% of which are TennCare patients), over 5,000 Medicare patients, and over 630 indigent/self-pay patients in 2013. Overall, this represents 85% of DRMC's patient mix for the year. DRMC is committed to continuing to care for these patients for all services. Table 24 below outlines the state and federal revenue programs in which DRMC participates, and the associated anticipated revenue for incremental diagnostic cardiac catheterizations and PCIs from the first year of the proposed project.

Table 24 – Dyersburg Regional Medical Center's State and Federal Revenue Programs

State & Federal Revenue Programs	Year 1 Estimated Revenue	Year 1 % of Total Project Revenue
Medicaid/TennCare	\$87,985	3%
Medicare	\$1,950,257	75%
Medically Indigent	\$83,126	3%

DRMC anticipates roughly 85% of its patient mix for this service to include Medicaid/TennCare, Medicare, and indigent/self-pay patients. The % of revenue coming from the Medicaid/TennCare and Medically Indigent patients in Table 24 above is reflective of the relatively lower reimbursement rates of associated with these insurance programs.

10. Provide copies of the balance sheet and income statement from the most recent reporting period of the institution and the most recent audited financial statements with accompanying notes, if applicable. For new projects, provide financial information for the corporation, partnership, or principal parties involved with the project. Copies must be inserted at the end of the application, in the correct alpha-numeric order and labeled as Attachment C, Economic Feasibility-10.

RESPONSE: Dyersburg Hospital Corporation d/b/a DRMC is audited once every 3-4 years, and is schedule for its audit in 2014. Therefore, no recent audited financial statements exist. A copy of the un-audited financials for 2013 are attached as Attachment C, 10 Financial Statements.

11. Describe all alternatives to this project which were considered and discuss the advantages and disadvantages of each alternative including but not limited to:

- a. A discussion regarding the availability of less costly, more effective, and/or more efficient alternative methods of providing the benefits intended by the proposal. If development of such alternatives is not practicable, the applicant should justify why not; including reasons as to why they were rejected.

RESPONSE:

As part of the determination to apply for a CON to provide therapeutic cardiac catheterization services, the leadership team at DRMC considered two alternatives to the project including: 1) Status Quo/Do Nothing, or to 2) Develop an Enhanced Network of Care for PCI. A summary of the practicality of each alternative can be found below:

- 1) **Status Quo/Do Nothing** – The possibility exists for DRMC to continue to provide only diagnostic cardiac catheterization services to the community it serves. However, as therapeutic cardiac catheterization services have been proven safe in labs without cardiac surgery on-site, it became clear that DRMC is currently NOT able to offer the recognized standard of care for the treatment of AMI to its community. Rather than be treated at DRMC, patients are transported via helicopter or ambulance to a hospital that resides outside of DRMC's service area. This creates delays in patient care causing additional damage to a patient's heart muscle, increases the risk associated with the patient's survival, and increases the cost of care. The cost associated with emergency ground and air transport from the DRMC market is roughly \$2,000 and \$30,000 per patient, respectively (depending on the retrieval and destination locations). A component of DRMC's mission statement involves ensuring quality care is delivered to the patients the hospital serves. With that in mind, a decision to NOT provide the recognized standard of care to DRMC's patient base was simply not acceptable. By providing this service at DRMC, the cost of care will be reduced while the quality of patient care would be improved. Therefore, this alternative was rejected as it is not considered a viable option.

- 2) **Develop an Enhanced Network of Care for PCI** – DRMC is part of Community Health Systems ("CHS") with headquarters in Franklin, Tennessee. Currently, CHS includes 132 hospitals in 29 states, with 11 based in the state of Tennessee. Nationally, a number of health systems are evaluating options to develop a network of care to serve the complex needs of their communities. Relative to cardiovascular services, a number of systems are evaluating whether to reduce the number of hospitals that offer open heart surgical services, while maintaining the therapeutic cardiac catheterization capabilities to create a 'hub and spoke' network. When changes like this are made, the hospitals that no longer offer cardiac surgery services continue to offer PCI to ensure the standard of care is available to their communities. Although DRMC is part of a larger health system, the closest system hospital, Regional Hospital of Jackson, is 47.8 miles from DRMC and a 51-minute drive. Additionally, the closest non-CHS hospital to DRMC that offers therapeutic cardiac catheterization services, Jackson-Madison County General Hospital is 48.4 miles from DRMC and a 55-minute drive. Given the distance and related delays to treatment involved, the development of an enhanced network to effectively provide this service to DRMC patients was not deemed acceptable. If DRMC pursued this option, the emergent ground and air transport costs would still be added on to the cost of care, thus increasing the cost necessarily to deliver the standard of care to the patients. Additionally, the time involved in transport would still exist, thus negatively impacting the quality of care offered when

compared to offering the service at DRMC. Therefore, this alternative was rejected and is not considered a viable option.

In an effort to provide the standard of care to its patients, while reducing the cost of care to the patients, DRMC submits that the best option involves offering therapeutic cardiac catheterization services at DRMC.

- b. **The applicant should document that consideration has been given to alternatives to new construction, e.g., modernization or sharing arrangements. It should be documented that superior alternatives have been implemented to the maximum extent practicable.**

RESPONSE: The DRMC proposal for advancement to offer therapeutic cardiac catheterization services does not include new construction. Rather, DRMC will provide this service in the existing space where the hospital provides its diagnostic cardiac catheterization service. Given existing patient volumes and projections based upon the addition of this service, DRMC will not require additional cardiac catheterization lab space for the foreseeable future. If there is a time when patient volumes dictate the necessity for additional cardiac catheterization lab space, DRMC will complete a separate certificate of need application.

CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE

1. **List all existing health care providers (e.g., hospitals, nursing homes, home care organizations, etc.), managed care organizations, alliances, and/or networks with which the applicant currently has or plans to have contractual and/or working relationships, e.g., transfer agreements, contractual agreements for health services.**

RESPONSE: Please see the list in Attachment C, (III) (1) Contractual Agreements.

2. **Describe the positive and/or negative effects of the proposal on the health care system. Please be sure to discuss any instances of duplication or competition arising from your proposal including a description of the effect the proposal will have on the utilization rates of existing providers in the service area of the project.**

RESPONSE: It is important to note that all payer patient origination data is not available at a ZIP Code or County level through the Tennessee Department of Health. In the absence of this data, DRMC is unable to determine the exact number of patients leaving its service area for therapeutic cardiac catheterization at a particular provider that offers the service. Without this data, DRMC is limited to simply evaluating the number of patients that are transferred from DRMC to another provider for a higher level of cardiovascular care (e.g., PCI, open heart, etc.). Patients that bypass DRMC via emergency transport or other means due to the hospital not offering the service would not be included in this transfer data.

When evaluating the service area for PCI services, DRMC reviewed its historical discharge data. The service area for PCI services includes six Counties in Tennessee, and one County in Missouri. Although DRMC cares for some patients residing outside of this proposed service area, it accounts for less than 3% of their total inpatient discharges in 2013. Therefore, DRMC is confident that this area is representative of its market for therapeutic cardiac catheterization patients in this proposal.

Using the 2012 Joint Annual Reports from the Tennessee Department of Health, the hospitals located in DRMC's service area are listed by County in Table 25 below. The table also indicates each hospital's cardiac catheterization capabilities.

Table 25 – Dyersburg Regional Medical Center Proposed Service Area Hospitals & Cardiac Catheterization Services²⁸

County Name	Hospital Name	Diagnostic Cardiac Catheterization Services	Therapeutic Cardiac Catheterization Services
Dyer County	Dyersburg Regional Medical Center	Yes	No
Crocket County	<i>No hospitals located within the County</i>	N/A	N/A
Gibson County	Gibson General Hospital	No	No
	Humboldt General Hospital	No	No
Lake County	<i>No hospitals located within the County</i>	N/A	N/A
Lauderdale County	Lauderdale Community Hospital	No	No
Obion County	Baptist Memorial Hospital – Union City	Yes	No
Pemiscot County, Missouri	Pemiscot County Memorial Hospital	No	No

As noted in Table 25 above, currently none of the hospitals residing in the DRMC service area offer therapeutic cardiac catheterization, and just one other hospital (Baptist Memorial Hospital – Union City) offers diagnostic cardiac catheterization services. Therefore, the approval of this application to allow DRMC to offer therapeutic cardiac catheterization would not create a duplication of services, nor competition with providers that exist in the service area. Additionally, the addition of this service at DRMC will have no impact on the utilization of services by providers located within the service area, as they do not currently offer this service.

Due to a lack of access to therapeutic cardiac catheterization services within the service area, patients must travel outside of their home County to seek this level of care from providers in other markets. For this reason, it can be reasonably assumed that the addition of a new service at DRMC will impact the utilization of this service at providers located outside of this market. However, the actual impact upon each provider is difficult to determine without market data noting the patient's origin at a ZIP Code or County level. Additionally, given the relatively high mortality rate for cardiovascular disease in the DRMC service area, it is likely that there are also patients that are currently not seeking or not receiving the appropriate level of care in a timely fashion. Therefore, a new therapeutic catheterization program at DRMC will increase access to care in the area, and enable DRMC to meet the volume projections and improve the healthcare for area residents, while

²⁸ Data Source: 2012 Joint Annual Reports from the Tennessee Department of Health

likely having a marginal effect on the utilization of services by providers located outside of the service area.

3. Provide the current and/or anticipated staffing pattern for all employees providing patient care for the project. This can be reported using FTEs for these positions. Additionally, please compare the clinical staff salaries in the proposal to prevailing wage patterns in the service area as published by the Tennessee Department of Labor & Workforce Development and/or other documented sources.

RESPONSE: DRMC commits to providing an appropriate staffing pattern to support a best-practice approach to care for both the emergent and elective PCI patient population. DRMC will ensure a full team complement of expert personnel consisting of at least four full-time team members available 24/7/365 in order to care for the STEMI/AMI patient population as part of an “on-call” team. This team will include a complement of staff including registered nurse(s), registered radiologic staff, and/or registered cardiovascular technologist(s) staff. The anticipated staffing pattern for those providing patient care for therapeutic cath at DRMC is set forth in Table 26 below.

Table 26 – Staffing Pattern for Therapeutic Catheterization Services at Dyersburg Regional Medical Center

Dyersburg Regional Medical Center Cardiac Cath Lab Staff	Current	Year 1	Year 2
Registered Nurse (RN)	3	4	4
Cardiovascular Radiology Technician (CVT)	1.5	2	2

The salaries for these positions will be comparable to those paid for personnel working in similar positions today at DRMC, within the State of Tennessee, and in the west Tennessee region, as illustrated in Table 27 below.

Table 27 – Comparison of Dyersburg Regional Medical Center Clinical Salaries to Prevailing Wage Patterns

Staff	DRMC		west Tennessee		State of Tennessee	
	Hourly	Annual	Hourly Mean	Annual Mean	Hourly Mean	Annual Mean
Registered Nurse (RN) ²⁹	\$26.78	\$55,702	\$25.10	\$52,220	\$26.85	\$55,800
Cardiovascular Radiology Technician (CVT) ³⁰	\$18.43	\$39,484	\$20.08	\$41,770	\$23.15	\$48,150

²⁹ TN Department of Labor & Workforce Development, Employment Security Division, Labor Market Information unit. Published July 2013. Statewide = <http://www.tn.gov/labor-wfd/wages/2013/PAGE0018.HTM>; West TN = <http://www.tn.gov/labor-wfd/wages/2013/PAGE0329.HTM>

³⁰ TN Department of Labor & Workforce Development, Employment Security Division, Labor Market Information unit. Published July 2013. Statewide = <http://www.tn.gov/labor-wfd/wages/2013/tennessee.pdf>; West TN = <http://www.tn.gov/labor-wfd/wages/2013/west.pdf>

4. Discuss the availability of and accessibility to human resources required by the proposal, including adequate professional staff, as per the Department of Health, the Department of Mental Health and Developmental Disabilities, and/or the Division of Mental Retardation Services licensing requirements.

RESPONSE: The applicant is confident that the human resources necessary to provide services for this proposal will be available and accessible to DRMC. The applicant commits to providing exceptional patient care and will utilize the expertise and experience of the cardiac catheterization staff having in-depth knowledge and "hands-on" experience in caring for a PCI patient population. DRMC intends to staff for 24/7/365 "on-call" for the STEMI/AMI patient population. Each clinical staff member of the cardiac catheterization team will meet all licensure requirements and will possess current state licensure as either a registered nurse (RN) and/or registered radiology technologist.

5. Verify that the applicant has reviewed and understands all licensing certification as required by the State of Tennessee for medical/clinical staff. These include, without limitation, regulations concerning physician supervision, credentialing, admission privileges, quality assurance policies and programs, utilization review policies and programs, record keeping, and staff education.

RESPONSE: DRMC is a licensed Tennessee hospital, duly licensed by the Tennessee Board for Licensing Healthcare Facilities. The applicant has reviewed and understands all licensing certification requirements for its medical and clinical staff as required by the State of Tennessee. It has appropriate quality assurance policies and programs, as well as utilization review policies and programs and an extensive staff education program. As previously mentioned, the applicant is Joint Commission accredited. The applicant's accreditation is attached. See Attachment C, (III) (5) The Joint Commission Accreditation.

6. Discuss your health care institution's participation in the training of students in the areas of medicine, nursing, social work, etc. (e.g., internships, residencies, etc.).

RESPONSE: Applicant provides training and education for student registered nurses, licensed practical nurses, radiology technicians and emergency medical service providers through a relationship with Dyersburg State Community College and Jackson State Community College.

7. (a) Please verify, as applicable, that the applicant has reviewed and understands the licensure requirements of the Department of Health, the Department of Mental Health and Developmental Disabilities, the Division of Mental Retardation Services, and/or any applicable Medicare requirements.

RESPONSE: Applicant has reviewed and understands the licensure requirements of the Department of Health, and all applicable Medicare requirements.

(b) Provide the name of the entity from which the applicant has received or will receive licensure, certification, and/or accreditation.

RESPONSE:

Licensure: Applicant is licensed by the Tennessee Board for Licensing Healthcare Facilities.

Accreditation: Applicant is fully accredited by the Joint Commission.

(c) If an existing institution, please describe the current standing with any licensing, certifying, or accrediting agency. Provide a copy of the current license of the facility.

RESPONSE: Applicant is in good standing with the Tennessee Board for Licensing Healthcare Facilities and The Joint Commission. Requested copies of applicant's license is attached as Attachment C, (III) 7 (c)(1)DRMC Hospital License.

(d) For existing licensed providers, document that all deficiencies (if any) cited in the last licensure certification and inspection have been addressed through an approved plan of correction. Please include a copy of the most recent licensure/certification inspection with an approved plan of correction.

RESPONSE: No Department of Health survey has been conducted in several years, and the hospital could not locate a copy of a statement of deficiencies. All deficiencies cited in the most recent Joint Commission survey have been corrected and accepted by the accrediting agency. All cited deficiencies were relatively minor. See Attachment C, (III) 7 (d) Joint Commission Survey.

- 8. Document and explain any final orders or judgments entered in any state or country by a licensing agency or court against professional licenses held by the applicant or any entities or persons with more than a 5% ownership interest in the applicant. Such information is to be provided for licenses regardless of whether such license is currently held.**

RESPONSE: There are no final orders or judgments against any professional licenses held by applicant or any person or entity as described in this question.

- 9. Identify and explain any final civil or criminal judgments for fraud or theft against any person or entity with more than a 5% ownership interest in the project**

RESPONSE: There are no final civil or criminal judgments for fraud or theft against any person or entity as described in this question.

- 10. If the proposal is approved, please discuss whether the applicant will provide the Tennessee Health Services and Development Agency and/or the reviewing agency information concerning the number of patients treated, the number and type of procedures performed, and other data as required.**

RESPONSE: As it currently does for all services, DRMC will provide the Tennessee Health Services and Development Agency and/or the reviewing agency information concerning the number of PCI patients treated, the number and type of procedures performed, and other data as required.

PROOF OF PUBLICATION

Attach the full page of the newspaper in which the notice of intent appeared with the mast and dateline intact or submit a publication affidavit from the newspaper as proof of the publication of the letter of intent.

A Publisher's Affidavit has been requested and will be submitted in a timely manner when received by the applicant.

DEVELOPMENT SCHEDULE

Tennessee Code Annotated § 68-11-1609(c) provides that a Certificate of Need is valid for a period not to exceed three (3) years (for hospital projects) or two (2) years (for all other projects) from the date of its issuance and after such time shall expire; provided, that the Agency may, in granting the Certificate of Need, allow longer periods of validity for Certificates of Need for good cause shown. Subsequent to granting the Certificate of Need, the Agency may extend a Certificate of Need for a period upon application and good cause shown, accompanied by a non-refundable reasonable filing fee, as prescribed by rule. A Certificate of Need which has been extended shall expire at the end of the extended time period. The decision whether to grant such an extension is within the sole discretion of the Agency, and is not subject to review, reconsideration, or appeal.

1. Please complete the Project Completion Forecast Chart on the next page. If the project will be completed in multiple phases, please identify the anticipated completion date for each phase.
2. If the response to the preceding question indicates that the applicant does not anticipate completing the project within the period of validity as defined in the preceding paragraph, please state below any request for an extended schedule and document the "good cause" for such an extension.

PROJECT COMPLETION FORECAST CHART

Enter the Agency projected Initial Decision date, as published in Rule 68-11-1609(c):
June 2014

Assuming the CON approval becomes the final agency action on that date; indicate the number of days **from the above agency decision date** to each phase of the completion forecast.

PHASE	DAYS REQUIRED	ANTICIPATED DATE (Month/Year)
1. Architectural and engineering contract signed		
2. Construction documents approved by the Tennessee Department of Health		
3. Construction contract signed		
4. Building permit secured		
5. Site preparation completed		
6. Building construction commenced		
7. Construction 40% complete		
8. Construction 80% complete		
9. Construction 100% complete (approved for occupancy)		
10. *Issuance of license	225	January 15, 2015
11. *Initiation of service	225	January 15, 2015
12. Final Architectural Certification of Payment		
13. Final Project Report Form (HF0055)	285	March 15, 2015

* For projects that do NOT involve construction or renovation: Please complete items 10 and 11 only.

List of Attachments

Attachment A, 4 Organizational Documentation

Attachment A, 6 Deed

Attachment B (III) (A) DRMC Plot Plan

Attachment B (IV) DRMC Cardiac Cath Lab Floor Plan

Attachment C Specific Cardiac Cath Criteria (3) Transfer Agreements

Attachment C (III) Proposed Service Area Map

Attachment C2, Economic Feasibility -2 Funding Letter

Attachment C, 10 Financial Statements

Attachment C, (III) (1) Contractual Agreements

Attachment C, (III) (5) The Joint Commission Accreditation

Attachment C, (III) 7 (c)(1)DRMC Hospital License

Attachment C, (III) 7 (d) Joint Commission Survey

600 ft x 720 ft

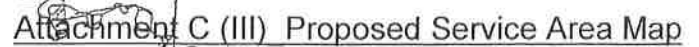
= 11.07 Acres

MAR 14 11 4 AM '10 SE



Attachment B (IV) DRMC Cardiac Cath Lab Floor Plan

DYERSBURG REGIONAL MEDICAL CENTER





400 Tickle Street • Dyersburg, TN 38024

March 4, 2014

Melanie M. Hill
Executive Director
Tennessee Health Services and Development Agency
Andrew Jackson Building, Ninth Floor
502 Deaderick Street
Nashville, TN 37243

Re: Dyersburg Regional Medical Center

Dear Ms. Hill:

I am Chief Financial Officer for Dyersburg Regional Medical Center ("DRMC"). DRMC has filed a certificate of need application for authorization to perform interventional cardiac catheterization procedures in its existing cardiac cath lab. The estimated project cost is \$364,763.00. Dyersburg Hospital Corporation, the owner of DRMC, will fund these project costs out of cash reserves, which are currently available for this purpose.

Please let me know if you have any questions or if additional information is needed. Thank you for your assistance.

Sincerely,

A handwritten signature in cursive script that reads "Meredith Malone".

Meredith Malone, CFO

GLORIA

D Y E R S B U R G R M C - D Y E R S B U R G , T N
INCOME STATEMENT D-57
FOR THE PERIOD ENDING FEBRUARY 28, 2014

0 1 8 0

DATE: 3/12/14
TIME: 18:27:35

	JANUARY	FEBRUARY	MARCH	APRIL	MAY	JUNE	JULY	AUGUST	SEPTEMBER	OCTOBER	NOVEMBER	DECEMBER	TOTAL
TOTAL PATIENT DAYS BY PA	1254	1048											2312
AVERAGE DAILY CENSUS	40.8	37.4											39.2
Patient Revenue:													
Inpatient Revenue:	2,147,357	1,840,772	0	0	0	0	0	0	0	0	0	0	3,988,129
Inpatient Routine	15,740,416	12,082,269	0	0	0	0	0	0	0	0	0	0	27,706,685
Inpatient Ancillary	28,071,743	27,335,554	0	0	0	0	0	0	0	0	0	0	55,407,297
Outpatient	45,843,516	41,258,595	0	0	0	0	0	0	0	0	0	0	87,102,111
Total Patient Revenue	11,410,513	8,646,078	0	0	0	0	0	0	0	0	0	0	20,056,591
Deductions From Revenue:	14,740,408	12,867,669	0	0	0	0	0	0	0	0	0	0	28,591,168
I/P - M/M Contractual	12,972,671	12,867,669	0	0	0	0	0	0	0	0	0	0	25,839,340
O/P - M/M Contractual	367	5,559	0	0	0	0	0	0	0	0	0	0	5,926
Courtesy Discounts	39,122,959	35,770,066	0	0	0	0	0	0	0	0	0	0	74,893,025
Total Deductions From Re	6,720,557	5,488,529	0	0	0	0	0	0	0	0	0	0	12,209,086
Net Pt Rev Before Bad Db	1,102,651	631,897	0	0	0	0	0	0	0	0	0	0	1,734,548
Provision for Bad Dbt	5,617,906	4,856,632	0	0	0	0	0	0	0	0	0	0	10,474,538
Net Pt Rev After Bad Dbt	22,949	24,958	0	0	0	0	0	0	0	0	0	0	47,907
Other Revenue	5,640,855	4,881,590	0	0	0	0	0	0	0	0	0	0	10,522,445
Net Revenue	1,564,138	1,424,948	0	0	0	0	0	0	0	0	0	0	2,989,146
Operating Expenses:	515,220	488,186	0	0	0	0	0	0	0	0	0	0	1,003,606
Salaries & Wages	21,132	12,100	0	0	0	0	0	0	0	0	0	0	33,292
Contract Labor	571,075	582,926	0	0	0	0	0	0	0	0	0	0	1,154,001
Supplies	241,202	110,744	0	0	0	0	0	0	0	0	0	0	371,946
Medical Spec Fees	422,570	460,079	0	0	0	0	0	0	0	0	0	0	882,649
Physician Recruiting	18,187	4,483	0	0	0	0	0	0	0	0	0	0	22,670
Repairs & Maintenance	186,656	116,191	0	0	0	0	0	0	0	0	0	0	302,817
Painting	23,700	7,123	0	0	0	0	0	0	0	0	0	0	30,823
Utilities	85,255	100,564	0	0	0	0	0	0	0	0	0	0	195,819
Other Operating Exp	82,350	82,350	0	0	0	0	0	0	0	0	0	0	165,090
Depreciation	512,530	489,370	0	0	0	0	0	0	0	0	0	0	1,006,902
HTSFR Incentives	(1,228,352)		0	0	0	0	0	0	0	0	0	0	(1,228,352)
Total Operating Expenses	3,031,144	3,899,265	0	0	0	0	0	0	0	0	0	0	6,930,409
Operating Margin	2,609,711	982,325	0	0	0	0	0	0	0	0	0	0	3,592,036
Rent	2,112,005	126,588	0	0	0	0	0	0	0	0	0	0	238,593
E.B.I.T.D.A.	2,497,706	855,737	0	0	0	0	0	0	0	0	0	0	3,353,443
Depreciation and Amortiz	2,199,446	558,141	0	0	0	0	0	0	0	0	0	0	595,856
E.B.I.T.	213,654	317,822	0	0	0	0	0	0	0	0	0	0	2,757,587
Interest	1,985,792	240,319	0	0	0	0	0	0	0	0	0	0	551,416
Pre-Tax Profit	236,421	236,421	0	0	0	0	0	0	0	0	0	0	2,226,111
Corp Mgmt Fees	676	700	0	0	0	0	0	0	0	0	0	0	472,842
TOTAL SURGERIES	393	330	0	0	0	0	0	0	0	0	0	0	1376
TOTAL ADMISSIONS	41	38	0	0	0	0	0	0	0	0	0	0	79
TOTAL DELIVERIES	6147	2029	0	0	0	0	0	0	0	0	0	0	9076
TOTAL O/P REGS INCL ALL	2127	1899	0	0	0	0	0	0	0	0	0	0	4026
TOTAL E.R. VISITS	61890	55766	0	0	0	0	0	0	0	0	0	0	117656
Total Paid Hours	61890	55766	0	0	0	0	0	0	0	0	0	0	117656
Total Paid & Contract Ro	349.56	348.53	0	0	0	0	0	0	0	0	0	0	349.13
TOTAL PAID & CONTRACT FT			0	0	0	0	0	0	0	0	0	0	

GLORIS

D Y E R S B U R G R N C - D Y E R S B U R G T N
INCOME STATEMENT D-57
FOR THE PERIOD ENDING DECEMBER 31, 2013

0 1 8 0

DATE: 3/12/14
TIME: 18:27:26

	JANUARY	FEBRUARY	MARCH	APRIL	MAY	JUNE	JULY	AUGUST	SEPTEMBER	OCTOBER	NOVEMBER	DECEMBER	TOTAL
TOTAL PATIENT DAYS BY PA	1171	1019	980	904	922	738	852	942	1026	835	819	927	11135
AVERAGE DAILY CENSUS	37.8	36.4	31.6	30.1	29.7	24.6	27.5	30.4	34.2	26.9	27.3	29.9	30.5
Patient Revenue:													
Inpatient Routine	1,791,219	1,591,403	1,472,391	1,466,988	1,515,152	1,287,552	1,440,613	1,651,335	1,763,923	1,426,650	1,436,140	1,678,291	18,519,657
Inpatient Ancillary	13,522,976	12,002,240	10,483,720	11,289,782	9,338,650	9,338,650	11,154,836	12,195,005	12,195,005	10,355,995	10,355,995	10,636,187	133,728,018
Outpatient	24,530,975	22,383,410	24,662,081	25,320,513	24,410,931	25,387,509	24,141,160	26,871,996	23,605,451	27,251,352	22,965,999	23,993,781	296,060,859
Total Patient Revenue	39,845,170	35,977,053	36,618,192	38,667,283	38,847,552	36,013,911	36,736,809	40,054,136	37,564,738	39,033,997	34,691,124	36,268,259	448,108,534
Deductions From Revenue:													
I/P - W/M Contractual	9,136,862	9,234,316	7,652,662	7,573,770	7,785,226	6,691,870	7,968,095	7,908,775	8,504,824	7,710,837	6,961,329	7,903,158	95,191,824
O/P - W/M Contractual	13,235,855	11,611,770	13,728,715	13,561,182	12,797,681	13,030,411	14,656,194	12,837,141	14,925,885	12,302,075	12,180,873	15,791,779	157,911,779
Other Contractual Adj.	10,883,993	9,493,786	9,249,786	11,746,936	10,591,538	9,992,630	10,913,825	12,241,964	10,285,033	10,731,645	9,842,122	10,013,301	125,975,357
Courtesy Discounts	4,254	4,358	13,885	2,412	5,117	3,090	5,251	7,133	(38,139)	10,829	3,986	5,234	27,410
Total Deductions From Re	33,320,564	30,344,230	30,645,946	32,484,300	31,169,562	30,130,587	31,917,582	34,814,066	31,688,859	33,379,196	29,109,512	30,102,566	379,106,370
Net P/R Rev Before Bad Db	6,524,606	5,632,823	5,972,246	6,182,983	5,677,990	5,883,324	4,819,227	5,240,370	5,875,889	5,654,801	5,581,612	6,165,693	69,202,164
Provision for Bad Db	935,549	883,760	1,285,769	697,475	924,351	620,422	959,838	760,165	956,355	810,179	953,249	1,089,204	10,912,316
Net P/R Rev After Bad Db	5,589,057	4,749,063	4,686,477	5,485,508	4,753,639	5,262,902	3,893,389	4,480,205	4,919,534	4,844,622	4,628,363	5,076,489	58,289,848
Other Revenue	29,357	30,307	20,098	32,097	28,636	30,670	24,382	28,073	32,005	28,591	26,073	23,368	351,637
Net Revenue	5,618,414	4,779,370	4,707,175	5,517,605	4,782,275	5,293,572	3,917,751	4,508,278	4,951,539	4,873,213	4,654,436	5,089,857	58,641,485
Operating Expenses:													
Salaries & Wages	1,559,347	1,404,800	1,395,317	1,468,315	1,489,075	1,354,916	1,401,005	1,443,157	1,425,359	1,429,530	1,408,079	1,513,526	17,334,376
Benefits	539,270	527,792	524,789	499,273	512,631	418,267	468,842	477,834	456,587	456,587	408,103	427,027	5,327,955
Contract Labor	0	0	0	0	0	0	0	0	0	0	0	0	0
Supplies	685,976	547,412	492,789	598,576	598,920	536,589	517,198	517,198	494,938	504,742	481,733	505,658	6,340,953
Medical Spec Fees	232,351	116,718	126,463	182,662	91,181	174,156	141,709	226,522	280,827	204,110	182,992	171,121	2,130,953
Physician Services	371,113	425,974	438,988	462,907	447,602	441,819	431,123	427,339	440,116	453,376	410,957	392,152	5,205,446
Physician Recruiting	16,441	1,400	5,250	7,495	2,500	30	117	4,642	101,967	142,993	17,154	4,100	1,369,971
Repairs & Maintenance	115,278	129,261	110,738	131,370	109,423	134,292	93,524	115,313	101,967	142,993	17,154	4,100	1,369,971
Marketing	12,138	7,885	4,879	9,611	5,727	15,629	5,940	5,940	10,675	14,657	3,580	115,952	1,101,927
Utilities	111,584	69,794	80,267	97,446	92,594	96,119	96,876	96,491	95,304	90,770	85,318	88,470	1,101,927
Other Operating Exp	78,360	75,417	46,810	78,746	46,810	56,538	66,810	43,085	58,826	55,603	62,960	52,517	728,434
Prop Taxes & Inc	488,625	477,604	474,902	497,222	488,186	476,999	493,655	483,182	493,655	493,612	475,102	103,342	5,425,812
HIT/IT Incentives	(1,720,253)	0	0	0	0	96,832	0	0	(389,724)	(4,730)	0	0	(2,017,875)
Total Operating Expenses	2,490,171	3,787,153	3,704,198	4,033,823	3,881,863	3,794,284	3,645,511	3,849,673	3,442,386	3,861,283	3,675,150	3,221,851	43,389,346
Operating Margin	3,128,243	992,217	1,002,977	1,483,782	998,412	1,499,288	202,240	656,605	1,529,183	1,011,930	979,286	1,864,006	15,252,139
Rent	112,715	114,548	126,087	125,826	111,739	124,228	124,622	97,336	113,963	111,650	126,377	120,405	1,411,496
P.B.I.T.D.A.	3,015,528	877,669	876,890	1,357,956	786,673	1,375,060	77,618	559,269	1,415,190	900,280	852,909	1,747,601	13,840,643
Depreciation and Amortiz	439,422	439,422	(21,116)	281,050	288,461	286,112	276,672	357,099	350,247	344,062	282,031	295,776	3,573,482
E.B.I.T.	2,580,002	438,247	899,005	1,066,126	498,212	1,088,948	302,110	1,066,126	1,066,126	556,218	600,878	1,451,825	10,267,161
Interest	328,932	323,496	337,879	332,892	350,646	346,071	348,219	347,735	343,262	360,636	337,525	371,487	4,168,940
Pre-Tax Profit	2,251,070	114,751	560,127	733,234	147,566	742,877	(546,973)	(281,607)	722,864	195,582	263,353	1,080,338	6,118,221
CORP WAGE FEES	217,573	217,573	217,573	217,573	217,573	217,573	217,573	217,573	217,573	217,573	217,573	217,573	2,278,572
TOTAL SUGARIES	726	713	758	832	645	721	619	762	695	786	642	553	8,452
TOTAL ADVERTISEMENTS	367	330	301	311	323	267	319	329	317	271	292	320	3,747
TOTAL DELIVERIES	32	39	26	35	32	40	42	47	41	35	54	35	461
TOTAL O/P REGS INCL ALL	5254	4655	5161	5191	6247	5495	6060	5073	5204	5666	4878	5536	64,420
TOTAL E.R. VISITS	2283	2111	2225	2111	2225	2150	2084	2214	2084	2116	1938	1871	25,565
Total Paid Hour	66336	58573	61573	59430	61661	58317	56853	59267	58000	59637	59932	59857	719,966
Total Contract Hours	1	1	1	1	1	1	1	1	1	1	1	1	1
Total Paid & Contract Ho	66337	58574	61574	59431	61662	58318	56854	59268	58001	59638	59933	59858	719,967
TOTAL PAID & CONTRACT FT	375,121	366,09	347,87	347,54	348,37	341,87	321,21	334,84	339,18	336,93	350,48	338,17	345,41

ASSETS
 THIS MONTH LAST MONTH INCR/(DECR)

Current Assets:			
Cash and cash equivalents	\$ 613,065	\$ 658,654	\$ (45,589)
Patient accounts receivable	14,789,207	13,445,749	1,343,458
Less: Allowance for bad debts	(4,481,949)	(4,300,154)	(181,795)
Prior yr cst rplc settlement a/y	(1,726,915)	(1,726,915)	00
Supplies	1,998,674	1,980,325	18,349
Prepaid expenses	344,623	373,328	(28,705)
Other current assets	(1,186,996)	395,847	(1,582,843)
Total Current Assets	11,349,709	11,826,834	(477,125)
Property & Equipment, at cost:			
Land and improvements	2,291,631	2,291,631	00
Buildings and improvements	39,231,282	39,218,819	12,463
Equipment and fixtures	18,176,478	18,086,592	89,886
Construction in progress	00	34,935	(34,935)
	59,699,391	59,631,977	67,414
Less accumulated depreciation and amortization	(35,480,567)	(35,238,552)	(242,015)
Net Property and Equipment	24,218,824	24,393,425	(174,601)
Other Assets:			
Investment in subs	10,000	10,000	00
Physician recruitment costs	290,435	273,935	16,500
Deferred MIS charges	1,850,066	1,840,091	9,975
Other deferred charges	60,208	57,896	2,312
Total Other Assets	2,210,709	2,181,922	28,787
Total Assets	\$ 37,779,242	\$ 38,402,181	\$ (622,939)

LIABILITIES

THIS MONTH

LAST MONTH

INCR./ (DECR)

Current Liabilities:

Current maturities of

Accounts payable

2,518,969

1,193,142

1,325,827

Accrued liabilities:

Employee compensation

1,908,270

1,641,408

266,862

Other accrued liabilities

206,562

778,143

(571,581)

Total Current Liabilities

4,633,801

3,612,693

1,021,108

Deferred Credits and

Intercompany Accounts

(8,973,123)

(6,134,011)

(2,839,112)

Total Liabilities

\$ (4,339,322)

\$ (2,521,318)

\$ (1,818,004)

Stockholders' Equity

Retained earnings-prior year

38,278,926

38,278,926

00

Retained earnings-curr year

3,839,638

2,644,573

1,195,065

Total Stockholders' Equity

42,118,564

40,923,499

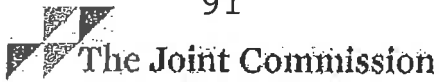
1,195,065

Total Liabilities and Equity

\$ 37,779,242

\$ 38,402,181

\$ (622,939)



Dyersburg Hospital Corporation
400 Tickle Street
Dyersburg, TN 38024

Organization Identification Number: 4049

Program(s)
Hospital Accreditation

Survey Date(s)
05/14/2013-05/17/2013

Executive Summary

As a result of the survey conducted on the above date(s), the following survey findings have been identified. Your official report will be posted to your organization's confidential extranet site. It will contain specific follow-up instructions regarding your survey findings.

If you have any questions, please do not hesitate to contact your Account Executive.

Thank you for collaborating with The Joint Commission to improve the safety and quality of care provided to patients.

The Joint Commission
Summary of Findings

DIRECT Impact Standards:

Program:	Hospital Accreditation Program	
Standards:	IC.02.02.01	EP2,EP4
	LS.02.01.20	EP1,EP31

INDIRECT Impact Standards:

Program:	Hospital Accreditation Program	
Standards:	EC.02.03.05	EP10
	EC.02.06.01	EP1
	LS.02.01.35	EP6
	RC.01.01.01	EP19
	RC.01.04.01	EP4
	RC.02.03.07	EP4
	TS.03.02.01	EP2

**The Joint Commission
Summary of CMS Findings**

CoP: §482.24 **Tag:** A-0431 **Deficiency:** Standard

Corresponds to: HAP

Text: §482.24 Condition of Participation: Medical Record Services

The hospital must have a medical record service that has administrative responsibility for medical records. A medical record must be maintained for every individual evaluated or treated in the hospital.

CoP Standard	Tag	Corresponds to	Deficiency
§482.24(c)(1)	A-0450	HAP - RC.01.01.01/EP19	Standard
§482.24(c)(2)	A-0450	HAP - RC.02.03.07/EP4	Standard

CoP: §482.41 **Tag:** A-0700 **Deficiency:** Standard

Corresponds to: HAP

Text: §482.41 Condition of Participation: Physical Environment

The hospital must be constructed, arranged, and maintained to ensure the safety of the patient, and to provide facilities for diagnosis and treatment and for special hospital services appropriate to the needs of the community.

CoP Standard	Tag	Corresponds to	Deficiency
§482.41(b)(1)(i)	A-0710	HAP - LS.02.01.20/EP1, EP31, LS.02.01.35/EP6	Standard

CoP: §482.51 **Tag:** A-0940 **Deficiency:** Standard

Corresponds to: HAP

Text: §482.51 Condition of Participation: Surgical Services

If the hospital provides surgical services, the services must be well organized and provided in accordance with acceptable standards of practice. If outpatient surgical services are offered the services must be consistent in quality with inpatient care in accordance with the complexity of services offered.

CoP Standard	Tag	Corresponds to	Deficiency
§482.51(b)	A-0951	HAP - IC.02.02.01/EP2, EP4	Standard

The Joint Commission Findings

Chapter: Environment of Care
Program: Hospital Accreditation
Standard: EC.02.03.05

Standard Text: The hospital maintains fire safety equipment and fire safety building features.
Note: This standard does not require hospitals to have the types of fire safety equipment and building features described below. However, if these types of equipment or features exist within the building, then the following maintenance, testing, and inspection requirements apply.

Primary Priority Focus Area: Communication

Element(s) of Performance:

10. For automatic sprinkler systems: Every quarter, the hospital inspects all fire department water supply connections. The completion dates of the inspections are documented.

Note: For additional guidance on performing tests, see NFPA 25, 1998 edition (Section 9-7.1).



Scoring

Category : A
Score : Insufficient Compliance

Observation(s):

EP 10

Observed in Document Review at Dyersburg Hospital Corporation (400 Tickle Street, Dyersburg, TN) site. The last quarterly testing of all fire department water supply connections was conducted on 2/26/13. The form stated "all connections checked". There were 3 connections, the vendor did not fill out the form which specified the three locations. Without the form being filled out verification of the specific locations was not available.

Chapter: Environment of Care
Program: Hospital Accreditation
Standard: EC.02.06.01

Standard Text: The hospital establishes and maintains a safe, functional environment.
Note: The environment is constructed, arranged, and maintained to foster patient safety, provide facilities for diagnosis and treatment, and provide for special services appropriate to the needs of the community.

Primary Priority Focus Area: Physical Environment

Element(s) of Performance:

1. Interior spaces meet the needs of the patient population and are safe and suitable to the care, treatment, and services provided.



Scoring

Category : C
Score : Insufficient Compliance

Observation(s):

The Joint Commission Findings

EP 1

Observed in Building Tour at Dyersburg Hospital Corporation (400 Tickle Street, Dyersburg, TN) site.
In the dock tank storage room there were several E size O2 cylinders that were leaning into the fence. They were at risk of falling over.

Observed in Building Tour at Dyersburg Hospital Corporation (400 Tickle Street, Dyersburg, TN) site.
In the dock tank storage room there were several H size NO2 cylinders that were not properly secured. They were at risk of being knocked over.

Observed in Building Tour at Dyersburg Hospital Corporation (400 Tickle Street, Dyersburg, TN) site.
In room B121 there were several H size CO2 cylinders. Several tanks had been removed. The chain was not repositioned. The tanks were loose and at risk of being knocked over.

Chapter: Infection Prevention and Control
Program: Hospital Accreditation
Standard: IC.02.02.01
Standard Text: The hospital reduces the risk of infections associated with medical equipment, devices, and supplies.

Primary Priority Focus Area: Infection Control

Element(s) of Performance:

2. The hospital implements infection prevention and control activities when doing the following: Performing intermediate and high-level disinfection and sterilization of medical equipment, devices, and supplies. * (See also EC.02.04.03, EP 4)



Note: Sterilization is used for items such as implants and surgical instruments. High-level disinfection may also be used if sterilization is not possible, as is the case with flexible endoscopes.

Footnote *: For further information regarding performing intermediate and high-level disinfection of medical equipment, devices, and supplies, refer to the website of the Centers for Disease Control and Prevention (CDC) at http://www.cdc.gov/hicpac/Disinfection_Sterilization/acknowledg.html (Sterilization and Disinfection in Healthcare Settings).

Scoring

Category : A
Score : Insufficient Compliance

4. The hospital implements infection prevention and control activities when doing the following: Storing medical equipment, devices, and supplies.

**Scoring**

Category : C
Score : Insufficient Compliance

Observation(s):

The Joint Commission Findings

EP 2

§482.51(b) - (A-0951) - §482.51(b) Standard: Delivery of Service

Surgical services must be consistent with needs and resources. Policies governing surgical care must be designed to assure the achievement and maintenance of high standards of medical practice and patient care.

This Standard is NOT MET as evidenced by:

Observed in Tracer Activities at Dyersburg Hospital Corporation (400 Tickle Street, Dyersburg, TN) site for the Hospital deemed service.

During tracer activities in Surgery it was observed that routine biological monitoring of immediate use (flash) sterilization cycles was being performed using a biological indicator (BI) placed in an open mesh container. According to staff, this was for the purpose of daily sterilizer efficacy testing. It was further observed that instruments were undergoing immediate use sterilization inside a closed rigid container designed for this purpose. According to AAMI ST79 10.7.4.1, "A representative of the same type of tray to be routinely processed through the flash sterilizer should be selected to serve as the PCD (BI challenge test tray)." Therefore, when performing daily sterilizer efficacy testing, the BI should have been placed inside the closed rigid container as this was the tray configuration used by the Hospital for immediate use sterilization.

Observed in Tracer Activities at Dyersburg Hospital Corporation (400 Tickle Street, Dyersburg, TN) site for the Hospital deemed service.

During tracer activities in Surgery (Sterile Processing) It was observed that a mechanical instrument washer was being used. However, according to staff, the effectiveness of the mechanical instrument washer was not being routinely tested. According to AAMI ST79 7.5.3.3, "Mechanical cleaning equipment should be tested upon installation, weekly (preferably daily) during routine use, and after major repairs." It should also be noted that various instrument washer testing products designed specifically for this purpose were commercially available.

Observed in Tracer Activities at Dyersburg Hospital Corporation (400 Tickle Street, Dyersburg, TN) site for the Hospital deemed service.

During tracer activities in Surgery it was observed that sterilized instruments and medical supplies were frequently being double packaged in paper-plastic pouches (peel packs). It was further observed that in many cases the inner package had been folded to varying degrees in order to accommodate placement into the outer package. However, according to AAMI ST79 8.3.4, "If the item is to be double-packaged, two sequentially sized pouches should be used (i.e., the sealed inner pouch should fit inside the other pouch without folding)."

EP 4

§482.51(b) - (A-0951) - §482.51(b) Standard: Delivery of Service

Surgical services must be consistent with needs and resources. Policies governing surgical care must be designed to assure the achievement and maintenance of high standards of medical practice and patient care.

This Standard is NOT MET as evidenced by:

Observed in Tracer Activities at Dyersburg Hospital Corporation (400 Tickle Street, Dyersburg, TN) site for the Hospital deemed service.

During tracer activities in Surgery (preoperative area) It was observed that Magill forceps were being stored in a code cart. It was further observed that the Magill forceps were not being stored inside any type of protective covering or wrapping. By not being stored inside any type of protective covering or wrapping, it was impossible to determine if the Magill forceps had been previously used and inadvertently placed back in the drawer. Furthermore, such storage conditions would have made it difficult to maintain the ongoing cleanliness of the Magill forceps.

Observed in Tracer Activities at Dyersburg Hospital Corporation (400 Tickle Street, Dyersburg, TN) site for the Hospital deemed service.

During tracer activities in Surgery (PACU) it was observed that Magill forceps and a plastic oral airway were being stored inside a code cart. It was further observed that both instruments were not being stored inside any type of protective covering or wrapping. By not being stored inside any type of protective covering or wrapping, it was impossible to determine if the Magill forceps and/or plastic oral airway had been previously used and inadvertently placed back in the drawer. Furthermore, such storage conditions would have made it difficult to maintain the ongoing cleanliness of these instruments.

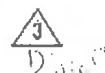
Observed in Tracer Activities at Riverside Surgery Center, a Dept of Dyersburg Regional M. C. (420 Wilkinson

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**The Joint Commission
Findings**

Drive, Dyersburg, TN) site for the Hospital deemed service.
During tracer activities it was observed that the bottom shelf of an endoscope storage cabinet was wet and dusty.
The endoscopes in the cabinet were being stored vertically and their tips were located close to the bottom shelf.

Chapter: Life Safety
Program: Hospital Accreditation
Standard: LS.02.01.20
Standard Text: The hospital maintains the integrity of the means of egress.
Primary Priority Focus Area: Physical Environment
Element(s) of Performance:

1. Doors in a means of egress are unlocked in the direction of egress.
(For full text and any exceptions, refer to NFPA 101-2000:
18/19.2.2.2.4)



Scoring
Category : A
Score : Insufficient Compliance

31. Exit signs are visible when the path to the exit is not readily apparent. Signs are adequately lit and have letters that are 4 or more inches high (or 6 inches high if externally lit). (For full text and any exceptions, refer to NFPA 101-2000: 7.10.1.2, 7.10.5, 7.10.6.1, and 7.10.7.1)



Scoring
Category : C
Score : Partial Compliance

Observation(s):

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The Joint Commission
Findings

EP 1

§482.41(b)(1)(i) - (A-0710) - (i) The hospital must meet the applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association. The Director of the Office of the Federal Register has approved the NFPA 101@2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the Federal Register to announce the changes.

This Standard Is NOT MET as evidenced by:

Observed in Building Tour at Dyersburg Hospital Corporation (400 Tickle Street, Dyersburg, TN) site for the Hospital deemed service.

There was an illuminated exit sign above the doors leading out of the rear exit in the Cardiac Cat Lab. The door was locked in the direction of egress. This was observed and then corrected at the time of survey.

EP 31

§482.41(b)(1)(i) - (A-0710) - (i) The hospital must meet the applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association. The Director of the Office of the Federal Register has approved the NFPA 101@2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the Federal Register to announce the changes.

This Standard is NOT MET as evidenced by:

Observed in Building Tour at Dyersburg Hospital Corporation (400 Tickle Street, Dyersburg, TN) site for the Hospital deemed service.

There were 4 exits leading out of the cafeteria. The right side exit in the main eating area did not have a lit exit sign above or near the exit door.

Observed in Building Tour at Dyersburg Hospital Corporation (400 Tickle Street, Dyersburg, TN) site for the Hospital deemed service.

There were 4 exits leading out of the cafeteria. The exit leading out of the private dining room did not have a lit exit sign above or near the exit door.

Chapter:	Life Safety
Program:	Hospital Accreditation
Standard:	LS.02.01.35
Standard Text:	The hospital provides and maintains systems for extinguishing fires.
Primary Priority Focus Area:	Physical Environment

99
The Joint Commission
Findings

Element(s) of Performance:

6. There are 18 inches or more of open space maintained below the sprinkler deflector to the top of storage.

Note: Perimeter wall and stack shelving may extend up to the ceiling when not located directly below a sprinkler head. (For full text and any exceptions, refer to NFPA 13-1999: 5-8.5.2.1)



Scoring

Category :

C

Score :

Partial Compliance

Observation(s):

EP 6

§482.41(b)(1)(i) - (A-0710) - (i) The hospital must meet the applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association. The Director of the Office of the Federal Register has approved the NFPA 101@2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/lbr_locations.html.

Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the Federal Register to announce the changes.

This Standard is NOT MET as evidenced by:

Observed in Building Tour at Dyersburg Hospital Corporation (400 Tickle Street, Dyersburg, TN) site for the Hospital deemed service.

There was not 18 inches or more of open space maintained below the sprinkler deflector to the top of storage in the kitchen dry storage room. This was observed and then corrected at the time of survey.

Observed in Building Tour at Dyersburg Hospital Corporation (400 Tickle Street, Dyersburg, TN) site for the Hospital deemed service.

There was not 18 inches or more of open space maintained below the sprinkler deflector to the top of storage in the Marketing storage room. This was observed and then corrected at the time of survey.

Chapter:

Record of Care, Treatment, and Services

Program:

Hospital Accreditation

Standard:

RC.01.01.01

Standard Text:

The hospital maintains complete and accurate medical records for each individual patient.

Primary Priority Focus Area: Information Management

Element(s) of Performance:

19. For hospitals that use Joint Commission accreditation for deemed status purposes: All entries in the medical record, including all orders, are timed.



Scoring

Category :

C

Score :

Insufficient Compliance

100
The Joint Commission
Findings

Observation(s):

EP 19

§482.24(c)(1) - (A-0450) - (1) All patient medical record entries must be legible, complete, dated, timed, and authenticated in written or electronic form by the person responsible for providing or evaluating the service provided, consistent with hospital policies and procedures.

This Standard is NOT MET as evidenced by:

Observed in Individual Tracer at Dyersburg Hospital Corporation (400 Tickle Street, Dyersburg, TN) site for the Hospital deemed service.

During tracer activity and review of the medical record of a patient in the intensive care unit, an order for a T&C had been authenticated but not dated or timed.

Observed in Individual Tracer at Dyersburg Hospital Corporation (400 Tickle Street, Dyersburg, TN) site for the Hospital deemed service.

During closed record review of a pediatric patient, a progress note written on 5/9 had not been timed.

Observed in Individual Tracer at Dyersburg Hospital Corporation (400 Tickle Street, Dyersburg, TN) site for the Hospital deemed service.

During an individual patient tracer it was observed that three physician progress notes were not timed.

Chapter: Record of Care, Treatment, and Services

Program: Hospital Accreditation

Standard: RC.01.04.01

Standard Text: The hospital audits its medical records.

Primary Priority Focus Area: Information Management

Element(s) of Performance:

4. The medical record delinquency rate averaged from the last four quarterly measurements is 50% or less of the average monthly discharge (AMD) rate. Each Individual quarterly measurement is no greater than 50% of the AMD rate. (See also MS.05.01.03, EP 3)

Note: To calculate the quarterly and annual average medical record delinquency rate, the Medical Record Statistics Form can be used.

This form is available at

http://www.jointcommission.org/Hospital_Medical_Record_Statistics_Form/



Scoring

Category : A

Score : Insufficient Compliance

Observation(s):

The staff in Medical Records verified that the numbers on the medical records delinquency form showing insufficient compliance were correct

Chapter: Record of Care, Treatment, and Services

Program: Hospital Accreditation

Standard: RC.02.03.07

Standard Text: Qualified staff receive and record verbal orders.

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The Joint Commission
Findings

Primary Priority Focus Area: Information Management

Element(s) of Performance:

4. Verbal orders are authenticated within the time frame specified by law and regulation.



Scoring

Category : C

Score : Insufficient Compliance

Observation(s):

EP 4

§482.24(c)(2) - (A-0450) - (2) All orders, including verbal orders, must be dated, timed, and authenticated promptly by the ordering practitioner or by another practitioner who is responsible for the care of the patient only if such a practitioner is acting in accordance with State law, including scope-of-practice laws, hospital policies, and medical staff bylaws, rules, and regulations.

This Standard is NOT MET as evidenced by:

Observed in Individual Tracer at Dyersburg Hospital Corporation (400 Tickle Street, Dyersburg, TN) site for the Hospital deemed service.

During tracer activity and review of the medical record of a patient in ICU, telephone orders received on 5/11 at 1125 and 1310 had not been authenticated within the 48 hour timeframe set by medical staff bylaws.

Observed in Individual Tracer at Dyersburg Hospital Corporation (400 Tickle Street, Dyersburg, TN) site for the Hospital deemed service.

During review of a closed medical record of a pediatric patient, telephone orders received on 5/9 at 1045 had not been authenticated within the 48 hour timeframe set by medical staff bylaws.

Observed in Individual Tracer at Dyersburg Hospital Corporation (400 Tickle Street, Dyersburg, TN) site for the Hospital deemed service.

During closed record review of a newborn transfer, telephone orders received on 4/19 at 0110 had not been authenticated within timeframe of 48 hours set by medical staff bylaws.

Observed in Individual Tracer at Dyersburg Hospital Corporation (400 Tickle Street, Dyersburg, TN) site for the Hospital deemed service.

During tracer activity and review of the medical record of a dialysis patient, a verbal order for dialysis treatment was received on 5/12 at 0826 but had not been authenticated within the timeframe of 48 hours set by medical staff bylaws.

Chapter: Transplant Safety

Program: Hospital Accreditation

Standard: TS.03.02.01

Standard Text: The hospital traces all tissues bi-directionally.

Primary Priority Focus Area: Information Management

Element(s) of Performance:

2. The hospital identifies, in writing, the materials and related instructions used to prepare or process tissues.



Not in writing prepare tissue

Scoring

Category : C

Score : Partial Compliance

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The Joint Commission
Findings

Observation(s):

EP 2

Observed in Document Review at Dyersburg Hospital Corporation (400 Tickle Street, Dyersburg, TN) site. During a review of the implantable tissue log in Surgery, staff stated that they do not routinely document the lot numbers of any solutions used in the preparation of implantable tissue.

Observed in Document Review at Dyersburg Hospital Corporation (400 Tickle Street, Dyersburg, TN) site. A review of the Hospital policy entitled "Use and Storage of Tissue Grafts and Human Tissue Products" revealed that there was no requirement for documenting the lot numbers of any solutions used in the preparation of implantable tissues.



May 31, 2013

Ben Youree, MBA/MHA
Chief Executive Officer
Dyersburg Hospital Corporation
400 Tickle Street
Dyersburg, TN 38024

Joint Commission ID #: 4049
Program: Hospital Accreditation
Accreditation Activity: Unannounced Full
Event
Accreditation Activity Completed:
05/17/2013

Dear Mr. Youree:

The Joint Commission would like to thank your organization for participating in the accreditation process. This process is designed to help your organization continuously provide safe, high - quality care, treatment, and services by identifying opportunities for improvement in your processes and helping you follow through on and implement these improvements. We encourage you to use the accreditation process as a continuous standards compliance and operational improvement tool.

With that goal in mind, your organization received Requirement(s) for Improvement during its recent survey. These requirements have been summarized in the Accreditation Report provided by the survey team that visited your organization.

Please be assured that The Joint Commission will keep the report confidential, except as required by law. To ensure that The Joint Commission's information about your organization is always accurate and current, our policy requires that you inform us of any changes in the name or ownership of your organization or the health care services you provide.

Please visit [Quality Check®](#) on The Joint Commission web site for updated information related to your accreditation decision.

Sincerely,

Mark G. Pelletier, RN, MS

Chief Operating Officer

Division of Accreditation and Certification Operations



May 31, 2013

Ben Youree
Chief Executive Officer
Dyersburg Hospital Corporation
400 Tickle Street
Dyersburg, Tennessee 38024

HCO ID: #4049

Dear Mr. Youree:

We appreciate your patience while we reviewed your clarification request regarding the findings of the May 14-17, 2013 full resurvey of your hospital program. Our review is now complete. Careful consideration was given to the original survey findings and the documentation submitted by your organization. Based on our review, below you will find information specific to the clarification submitted and the impact on your organization's final report.

- LS.02.01.35, EP 6 – The clarification submitted at this standard/ep was accepted. The documentation submitted for review, as well as the audit data, contained sufficient evidence to demonstrate that your organization was over 90% compliant with the requirements of this EP at the time of your survey. As a result, LS.02.01.35 is no longer listed as a Requirement for Improvement on your official accreditation report.

Please feel free to contact me at 630-792-5737 with any questions.

Sincerely,

Kelli Jacobs

Kelli Jacobs
Sr. Account Executive
Accreditation and Certification Operations

cc: Paul Ziaya, Field Director, The Joint Commission
Martin Feldman, MD, Field Representative, The Joint Commission
Jane Burdick, Field Representative, The Joint Commission
David Sladewski, Field Representative, The Joint Commission

AFFIDAVIT

FOR ATTORNEY EYES ONLY

STATE OF TENNESSEE

COUNTY OF DYER

Ben Youree, being first duly sworn, says that he/she is the applicant named in this application or his/her/its lawful agent, that this project will be completed in accordance with the application, that the applicant has read the directions to this application, the Rules of the Health Services and Development Agency, and T.C.A. § 68-11-1601, *et seq.*, and that the responses to this application or any other questions deemed appropriate by the Health Services and Development Agency are true and complete.

BY
SIGNATURE

CEO
TITLE

Sworn to and subscribed before me this 11th day of March, 2014 a Notary Public in and for Dyer County, Tennessee.

Susan Stover
NOTARY PUBLIC

My commission expires 1-18-16



COPY SUPPLEMENTAL-1

Dyersburg Regional Medical ctr.

CN1403-007

SUPPLEMENTAL RESPONSES**CERTIFICATE OF NEED APPLICATION****FOR****DYERSBURG REGIONAL MEDICAL CENTER****Project No. CN1403-007****Expansion Of Existing Cardiac Catheterization Service
to Include Interventional Cardiac Catheterization****Dyer County, Tennessee****March 25, 2014****Contact Person:**

**Jerry W. Taylor, Esq.
Stites & Harbison, PLLC
401 Commerce Street, Suite 800
Nashville, Tennessee 37219
615-782-2228**

1. Section A, Item 3

Please provide the names of the owners (5% interest or greater) of Community Health System and indicate their percentage of ownership.

Community Health Systems, Inc. is a publicly traded company with thousands of shareholders. The identification of those shareholders with 5% or greater shares is not readily available.

Please list hospitals owned by Community Health Systems in Tennessee and Missouri.

A list is attached following this page.

Please discuss the proposed organizational and business relationships among these entities in such a manner that their affiliation with project can be understood. An organization chart will be helpful.

Community Health Systems, Inc. is a publicly traded company. Through its various affiliated entities CHS owns, operates or leases 206 hospitals in 29 states as of February 2014. Twenty of these hospitals are in Tennessee. Each CHS hospital is operationally independent, with certain administrative support services supplied by CHS and its affiliates. Ownership information for the applicant and an organizational chart for CHS are attached following this page.

2. Section A, Item 9 Bed Complement Data

The bed complement data chart is noted. Please complete the "Total Beds at Completion" column.

A revised Bed Complement Data Chart is attached following this page as a replacement page for the application.

Tennessee

Dyersburg Regional Medical Center, Dyersburg

Gateway Medical Center, Clarksville

Harton Regional Medical Center, Tullahoma

Haywood Park Community Hospital, Brownsville

Henderson County Community Hospital, Lexington

Heritage Medical Center, Shelbyville

Jamestown Regional Medical Center, Jamestown

Jefferson Memorial Hospital, Jefferson City

LaFollette Medical Center, LaFollette

Lakeway Regional Hospital, Morristown

McKenzie Regional Hospital, McKenzie

McNairy Regional Hospital, Selmer

Newport Medical Center, Newport

North Knoxville Medical Center, Powell

Physicians Regional Medical Center, Knoxville

Regional Hospital of Jackson, Jackson

SkyRidge Medical Center, Cleveland

Turkey Creek Medical Center, Knoxville

University Medical Center, Lebanon

Volunteer Community Hospital, Martin

Missouri

Moberly Regional Medical Center, Moberly

Northeast Regional Medical Center, Kirksville

Poplar Bluff Regional Medical Center, Poplar Bluff

Twin Rivers Regional Medical Center, Kennett

**DYERSBURG HOSPITAL CORPORATION
OWNERSHIP INFORMATION**

Name of Entity: **Dyersburg Hospital Corporation** (TN Corp.) (EIN: 42-1557536)
d/b/a Dyersburg Regional Medical Center
Corporate Address: 4000 Meridian Blvd., Franklin, TN 37067
Facility Address: 400 Tickle Street, Dyersburg, TN 38024

The disclosing entity is wholly owned by:

Community Health Investment Company, LLC (DE Ltd. Liability Co.) (EIN: 76-0152801)
4000 Meridian Blvd., Franklin, TN 37067

Which is wholly owned by:

CHS/Community Health Systems, Inc. (DE Corp.) (EIN: 76-0137985)
4000 Meridian Blvd., Franklin, TN 37067

Which is wholly owned by:

Community Health Systems, Inc. (DE Corp.) (EIN: 13-3893191)
a publicly traded company, trading under the symbol of "CYH" on the NYSE
4000 Meridian Blvd., Franklin, TN 37067

Dyersburg Hospital Corporation d/b/a Dyersburg Regional Medical Center

The corporation's officers and directors are:

<u>NAME</u>	<u>TITLE</u>	<u>STREET ADDRESS</u>
W. Larry Cash	Director and President	4000 Meridian Blvd. Franklin, TN 37067
Martin Schweinhart	Director and Executive Vice President	4000 Meridian Blvd. Franklin, TN 37067
Rachel A. Seifert	Director, Executive Vice President and Secretary	4000 Meridian Blvd. Franklin, TN 37067
James W. Doucette	Senior Vice President and Treasurer	4000 Meridian Blvd. Franklin, TN 37067
Kevin Hammons	Senior Vice President	4000 Meridian Blvd. Franklin, TN 37067
Christopher G. Cobb	Assistant Secretary	4000 Meridian Blvd. Franklin, TN 37067

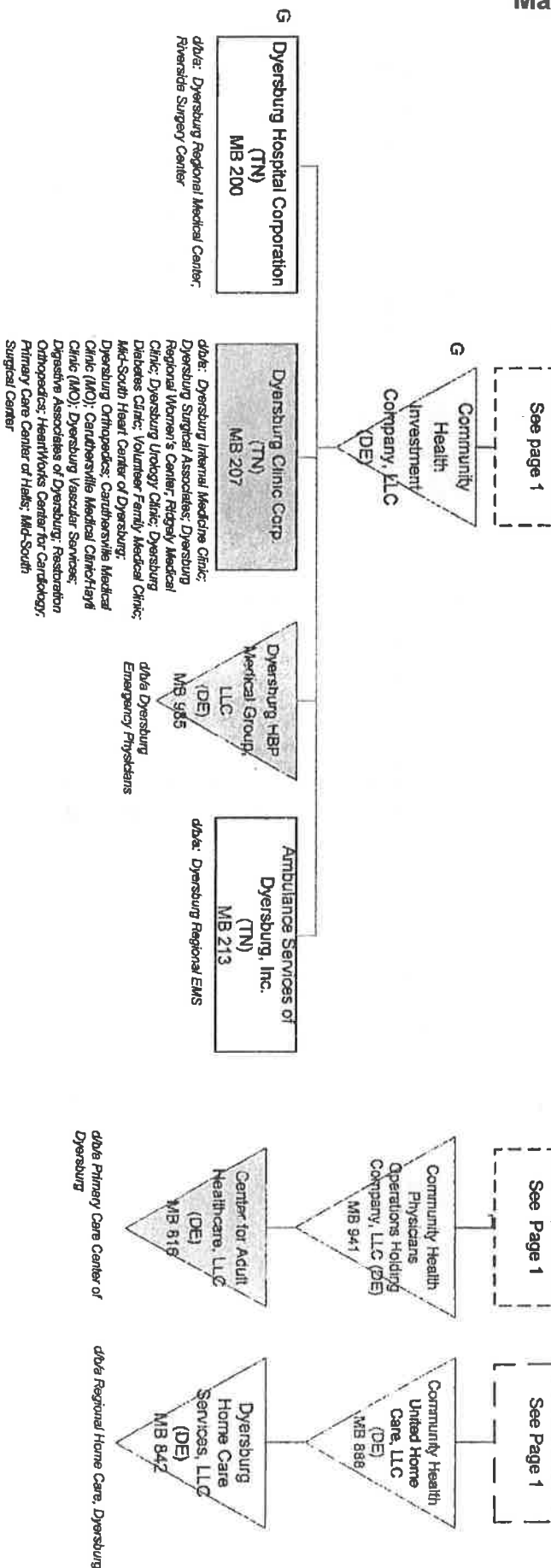
Organizational Chart



12/31/13
Page 1

TENNESSEE
Dyersburg

112



3. Section A, Applicant Profile, Item 13

The applicant's contractual relationships with Bluecare, United Community Healthcare Plan and TennCare Select are noted. However, new TennCare contracts will take effect January 1, 2015 with full statewide implementation for AmeriGroup, BlueCare Tennessee and United Healthcare. Please indicate if the applicant intends to contract with AmeriGroup. If so, what stage of contract discussions is the applicant involved with AmeriGroup?

DRMC has a strong interest in being part of the AmeriGroup network when it goes statewide. DRMC is in the early stages of discussions with AmeriGroup representatives towards that end.

Please clarify if the applicant has a Medicaid contract with Missouri.

Yes, DRMC is a contracted Medicaid provider with the State of Missouri.

What type of contracts does DRMC have with Missouri insurance organizations?

DRMC does not maintain contracts with any Missouri based health plans. Most plans will pay normal reimbursement for emergency treatment or admissions. Elective admissions may be treated by a Missouri insurer as out-of-network.

4. Section B, Project Description, Item 1

Your response is noted. Please provide an executive summary not to exceed two (2) pages. Please list the following areas as headers and address each area under the appropriate header: proposed services and equipment; ownership structure; service area; need; existing resources; project cost; funding; financial feasibility; and staffing.

A revised Executive Summary is attached following this response.

What are the hours of DRMC's cardiac catheterization lab?

The existing cardiac catheterization lab's normal operating hours are Monday through Friday from 7:00am to 4:00pm.

What plans does the applicant have for therapeutic catheterization procedures during non-operating times?

DRMC plans to have on-call availability for after-hours Monday through Friday, weekends, and observed holidays. The on-call availability will include an interventional cardiologist, and cardiac catheterization lab team comprised of nursing and technical personnel who will respond before and after the "normal operating hours" listed above.

I. Provide a brief executive summary of the project not to exceed two pages. Topics to be included in the executive summary are a brief description of proposed services and equipment, ownership structure, service area, need, existing resources, project cost, funding, financial feasibility and staffing.

RESPONSE:

Ownership Structure

Dyersburg Regional Medical Center ("DRMC") is a 225-bed community hospital located in Dyersburg, Tennessee. DRMC is owned by Dyersburg Hospital Corporation, which is owned by an affiliate of Community Health Systems, Inc. ("CHS"), which is headquartered in Franklin, Tennessee. CHS owns, operates or leases 206 hospitals in 29 states as of February 2014. As a member of CHS, DRMC is in a position to benefit from the experience gained by health system hospitals, which will be particularly useful in regards to the applicant's proposal to expand its service capabilities with this application.

Service Area

DRMC serves the needs of over 190,000 people residing in a 7-County area in west Tennessee and Missouri. The Counties in DRMC's service area include Crocket, Dyer, Gibson, Lake, Lauderdale, and Obion Counties in Tennessee, and Pemiscot County in Missouri. Currently, DRMC is one of only two hospitals located within this 7-County area that have a cardiac catheterization lab, with neither hospital having therapeutic cardiac catheterization ("PCI") or open heart surgery capabilities. When evaluating the demographics of the DRMC service area, it is clear that the applicant is providing healthcare services to a patient population that has significantly higher rates of mortality from heart disease and acute myocardial infarctions ("AMI," "STEMI," or heart attack), higher rates of poverty, and a higher percentage of elderly when compared to the state and the nation. In addition, all of the Counties in DRMC's service area are designated as medically underserved areas ("MUAs") by the Health Resources and Services Administration ("HRSA"). MUAs are characterized by HRSA as having too few primary care providers, high infant mortality, high poverty and/or high elderly population¹. These factors contribute to a population with a heightened need for improvements to access to care that will aid in improving the health status of the community.

Existing Resources

Patients that require treatment options beyond the scope of services offered by DRMC -- PCI or open heart surgery -- are transferred or referred to a provider based in a County outside of the service area. This situation causes delays to treatment, adds unnecessary costs to patient care with increased EMS transports over longer distances, and places residents in the DRMC service area in a situation that involves unnecessary risks. According to data from the National Registry of Myocardial Infarction ("NRM"), patients who are transferred for primary PCI are treated 71 minutes later than patients who receive primary PCI locally. Additionally, the NRM registry demonstrates that a door-to-balloon time of 2.5 to 3 hours, as seen in patients transferred for PCI, is associated with a 60% increase in risk-adjusted mortality compared with a door-to-balloon time of less than 2 hours². With the approval to initiate PCI services at DRMC, patients that reside in the service area

¹ "Find Shortage Areas: MUA/P by State and County," Health Resources and Services Administration, <http://muafind.hrsa.gov/index.aspx>, Accessed 23 January 2014.

² Reference: Wharton, Thomas P., "The Case for Community Hospital Angioplasty," *Circulation*. 2005; 112: 3509-3534.

would now be able to travel to a hospital offering PCI services in less than 1 hour, with the majority of residents able to travel to DRMC in less than 30 minutes.

Proposed Services, Equipment, and Project Cost

Due to the initiation of a diagnostic cardiac catheterization service at DRMC in 2009, the applicant would require a relatively minimal investment to advance its capabilities to offer PCI. DRMC will not need to renovate its physical plant to offer the service, and therefore has no renovation or construction costs associated with this project. The total investment in equipment to introduce PCI services at DRMC is \$200,000. Given the relatively low cost of entry, the initiation of a PCI services would be financially viable decision for the applicant. Additionally, PCI services will allow DRMC to better utilize existing space and equipment that is already in place for the diagnostic catheterization program. At the same time, the inability to advance DRMC's capabilities to offer PCI services has the potential to cause erosion to the volume of diagnostic catheterization currently performed.

Staffing

DRMC has a complement of experienced personnel in place to manage the existing diagnostic cardiac catheterization lab. With approval of this application, DRMC plans to add the additional personnel required to ensure the hospital has an adequate number of nurses and radiology technicians to continue to provide services during normal hours, but now also to care for an emergent patient population that can present to the hospital at any time.

Financial Feasibility and Funding

With an existing diagnostic cardiac catheterization service at DRMC, the required investment to advance services to offer PCI is considered relatively minimal. The project will not require changes to the current facility, which reduces the investment significantly. The total cost for equipment for this project is estimated to total \$200,000. With a limited investment required to expand DRMC's capabilities in its existing cardiac catheterization lab space, the applicant expects to achieve a positive ROI even within the first full year of operation. This project is expected to be fully funded using the applicant's cash reserves.

Need

Through an evaluation of patient transfer data, it is clear that DRMC has a high volume of patients with cardiovascular disease presenting to the hospital. In fact, in 2013 alone DRMC transferred over 1,000 patients for cardiovascular reasons. With non-invasive testing and diagnostic catheterization capabilities on-site, clearly a number of patients presenting to DRMC are considered high risk or are in need of a higher level of cardiac care that is not offered at the hospital today. The market potential for an expansion in capabilities to offer PCI services indicates DRMC will meet the established volume thresholds for a PCI program within its first full year of operation. With no PCI program in the DRMC service area, DRMC, with the approval to offer PCI, will have no effect on provider volumes for those that are located in the seven counties it serves. Additionally, given the significantly high mortality rates for heart disease and AMI in the region, a new PCI program will improve access to necessary care while having a marginal effect on programs located outside of the DRMC market.

In summary, the proposed project will improve access to the recognized standard of care in the treatment of AMI, is economically feasible, provides a necessary service to Tennesseans, and reduces unnecessary risks to the patient population DRMC serves. For these reasons and more, the applicant requests that the Tennessee Health Services and Development Agency approve its

March 25, 2014

application to expand its capabilities to offer therapeutic cardiac catheterization services to the communities it serves. **10:35am**

5. Section B, Project Description, Item II A.

The applicant states the inability to provide therapeutic cardiac catheterization (PCI) services will have the potential to erode DRMC's diagnostic catheterization volumes thus impacting the program's long-term viability. With this in mind, how has the volumes and viability of the program been impacted since the implementation of CN-0509-83A for the Initiation of Diagnostic Cardiac Catheterization without therapeutic catheterization?

Since the initiation of diagnostic cardiac catheterization services at DRMC, the hospital has experienced positive responses from service area residents now that patients can receive a higher level of cardiac care closer to home. At the same time, this logical advancement in services put DRMC in a better position to secure cardiologist coverage for the hospital. However, as the recognized standard of care has changed and as cardiac catheterization labs offering PCI without surgery on-site have been proven safe, DRMC has been challenged to maintain consistent cardiology coverage over time due to limitations on the program's capabilities. Additionally, patients can reasonably question why they would need to potentially endure two cardiac catheterization procedures when the applicant could be in a position to provide therapeutic treatment options in the same setting.

As fewer cardiologists come out of training with just invasive ("diagnostic cardiac catheterization") capabilities, DRMC expects this challenge to continue for labs without therapeutic capabilities. Since the 1990's, the number of cardiologists coming out of training has been below historic levels. Annually, roughly 750 physicians graduate from general cardiovascular disease training programs, with nearly 50% of them obtaining further training in interventional cardiology or clinical care electrophysiology¹. This statistic alone may reasonably exclude DRMC from attracting half of the new cardiologists coming out of training given the absence of therapeutic cardiac catheterization capabilities at the hospital. In fact, as referenced in this application, a number of cardiologists working in west Tennessee have expressed interest in working at DRMC if the program expands to offer therapeutic cardiac catheterization. Without these capabilities, these physicians would not be interested in actively practicing at the hospital on a consistent basis. The demands on these specialists' time are many, and practicing at a lab with just diagnostic capabilities would require these physicians to endure a significantly greater travel burden while actively practicing at a site offering therapeutic treatments as well in an effort to maintain their interventional skillset.

This situation would place DRMC at a disadvantage when working to secure cardiology coverage for the hospital. That, coupled with the current inability to offer the standard of care to STEMI patients has the potential to erode diagnostic volumes and thus impact the program's long term viability.

6. Section C. 1. Need (Specific Criteria - Cardiac Catheterization) Item 3

The transfer agreements to three (3) hospitals are noted. Please complete the following table:

A completed table appears following this response.

¹ *J Am Coll Cardiol.* 2009;54(13):1195-1208. doi:10.1016/j.jacc.2009.08.001

Hospital	Distance from DRMC miles / Air Nautical miles	Emergency travel time from DRMC to receiving facility by air in minutes flight time / Total transfer time*	# of transfers in 2013 by air	Emergency travel time from DRMC to receiving facility by ground ambulance in minutes	# of transfers in 2013 by ground	# of transfers in 2013 for open heart surgery	# of transfers in 2013 for therapeutic catheterization	\$ of transport by Ground Ambulance / Air Ambulance
Regional Hospital Jackson	49.7 / 33.1	19.9 / 46.9	12	49	443	0	20	\$1681.80 / \$21,000
Methodist University	77.2 / 60.6	38.8 / 65.8	1	81	51	1	1	\$2066.80 / \$25,000
St Francis - Memphis	87 / 64.7	36.3 / 63.3	2	85	10	0	0	\$2204.00 / \$25,000
Vanderbilt University	173.7 / 125.5	75.3 / 102.3	2	155	15	1	0	\$3417.80 / \$28,000
<p>* Total transfer time includes loading and unloading on both ends. Flight time is actual time in the air</p> <p>Total flights in 2013 = 174 (31 of these were from the scene)</p> <p>* DRMC does not know definitively which of these transfers resulted in an open heart surgery. This is the best estimation based on available information.</p> <p>* DRMC does not know definitively which of these transfers resulted in a PCI procedure. This is the best estimation based on available information.</p> <p>*This represents charges and not actual cost</p>								

MAR 25 14 10:35

It appears Vanderbilt Medical Center is not within the 60 minute compliance for patient transfer. Please clarify the reason the applicant does not have a transfer agreement with a closer Shelby County tertiary hospital with similar services.

DRMC does have a transfer agreement with St. Francis Hospital, which is a Shelby County Hospital with similar services. A copy of the transfer agreement is included in Attachment C Specific Cardiac Cath Criteria (3) Transfer Agreements in the application.

Please discuss the services available at Vanderbilt Medical Center, the Regional Hospital of Jackson and St. Francis Hospital for patients who are transferred for higher levels of heart care from DRMC.

Vanderbilt Medical Center located in Davidson County offers a full complement of cardiovascular services, including: general cardiology, diagnostic and therapeutic cardiac catheterization, open heart surgery, congenital heart care, heart transplant services, transcatheter aortic valve replacement, and cardiac rehabilitation services.

St. Francis Hospital located in Shelby County offers a full complement of cardiovascular services, including: general cardiology services, diagnostic and therapeutic cardiac catheterization, open heart surgery, and cardiac rehabilitation services.

Regional Hospital of Jackson located in Madison County offers a more limited complement of cardiovascular services, including: general cardiology, diagnostic and therapeutic cardiac catheterization, and cardiac rehab services.

It appears the three provided hospital transfer agreements were signed from March 2013 to May 2013. Please list the prior hospital transfer agreements for DRMC from the implementation of CN0509-083A of May 4, 2010 to March 2013.

The hospital is unable to locate any such transfer agreements prior to those provided. All of the hospital's transfer agreements were recently updated, and that is why the ones provided all had signature dates between March and May of 2013.

If the hospitals with transfer agreements with DRMC prior to March 2013 are different from the existing hospitals, why did the DRMC seek other hospitals to transfer heart patients?

N/A. Please see immediately preceding response.

Please provide a letter of interest from a Madison and/or Shelby County hospital regarding a possible transfer agreement specific to open heart surgery.

Not all hospitals require a transfer agreement be specific to open heart surgery. DRMC has transferred patients to both West Tennessee Health Care d/b/a Jackson Madison County General Hospital (Madison County) and St. Francis Hospital (Shelby County) for open heart surgery. A letter on behalf of Methodist University Hospital expressing interest in entering into such a Transfer Agreement with DRMC is attached following this response.

March 25, 2014

10:35am



March 21, 2014

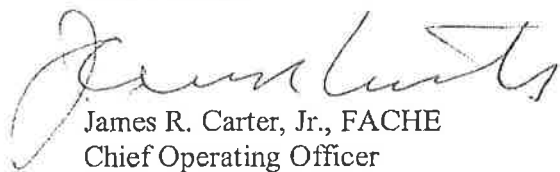
Ben Youree
Chief Executive Officer
Dyersburg Regional Medical Center
400 East Tickle Street
Dyersburg, TN 38024

RE: Cardiothoracic Surgical Coverage

Dear Mr. Youree,

Methodist University Hospital will provide cardiothoracic surgical coverage for Dyersburg Regional Medical Center through an Emergent Transfer Agreement. A definitive agreement will be executed in the near future when the parties reach mutually agreeable terms.

Respectfully,

A handwritten signature in dark ink, appearing to read "James R. Carter, Jr.", written over a light blue horizontal line.

James R. Carter, Jr., FACHE
Chief Operating Officer

cc: file

University Hospital

1265 Union Avenue • Memphis, Tennessee 38104 • 901-516-7000 • www.methodisthealth.org

7. Section C. 1. Need (Specific Criteria - Cardiac Catheterization) Item 7

Please discuss DRMC's plan to maintain qualified cardiologist for the proposed services.

There are two categories of cardiologists involved in this project: (1) the invasive cardiologists who are performing the diagnostic procedures now at DRMC, and (2) the interventional cardiologists who will perform the interventional PCI procedures if this application is approved.

The invasive cardiologists now on staff and performing diagnostic procedures will be maintained under the current arrangements and will continue performing diagnostic procedures even if and when this application is approved.

The interventional cardiologists will be recruited and brought onto the medical staff to perform the interventional procedures if and when this application is approved. Several interventional Cardiologists that meet these guidelines have expressed an interest in working at a new PCI program at DRMC, but without the approval to proceed it is deemed premature at this point to contract with these eligible physicians. DRMC intends to maintain compliance regarding the minimum physician requirements of at least two (2) interventional cardiologists with at least one having performed an average of 75 therapeutic cardiac procedures over the most recent five year period. DRMC affirms the cardiologists that will be providing therapeutic cardiac service will be either board eligible or board certified in cardiology and other relevant cardiac subspecialties.

If a cardiologist unexpectedly leaves DRMC, what would DRMC do to ensure the continuity of the proposed service?

An unexpected loss of a key medical staff member is always a possibility at any hospital, and the executive management at DRMC is prepared to take all necessary steps to ensure continuity of patient care is maintained during any period of unexpected physician loss while simultaneously putting in place recruitment efforts to replace the medical staff physician. Of course it is next to impossible to recruit an interventional cardiologist until the hospital has CON approval or an interventional program is in place. As discussed above, interventional cardiologists meeting the education, training and experience requirements will be recruited and maintained on the medical staff if this application is approved.

8. Section C. 1. Need (Specific Criteria - Cardiac Catheterization) Item 9

Table 5 of distances to nearest PCI centers and cardiac services are noted. It appears the nearest facility with open heart surgery capabilities is Jackson-Madison County General Hospital in Jackson, TN. Please explain why there is not a transfer agreement with this facility when it is best to be under 60 minutes transfer time for heart patients.

A transfer agreement is not necessary for the transfer of patients for open heart surgery at West Tennessee Healthcare d/b/a Jackson Madison County General Hospital, because WTHC has in effect an Auto-Acceptance Policy for Cardiology-STEMI Transfers. A copy of the policy is attached following this response. DRMC transfers a number of heart attack patients to Jackson Madison County General Hospital.

West Tennessee Healthcare
WTHVC POLICY AND PROCEDURE

TITLE: <u>Auto-Accept for Cardiology-Assigned & Unassigned</u> <u>- STEMI Transfer</u> CATEGORY: <u>Care Coordination</u>	POLICY NO.: _____ PAGE(S): <u>2</u> EFFECTIVE: <u>4/23/2012</u> REVIEWED: <u>11/1/2013</u> REVISED: <u>11/1/2013</u>
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PURPOSE: To establish an Auto-Acceptance process for referring facilities to expedite E.D. to E.D. transfers of Cardiology/STEMI patients to Jackson Madison County General Hospital. (JMCGH).

POLICY: West Tennessee Heart and Vascular Center and Emergency Department at JMCGH initiated the Auto-Accept process for Cardiology transfers only. Once contacted by the referring facility of a patient needing Cardiology services at JMCGH, the IC and/or ED physician can accept the patient directly. Cardiologists are responsible to respond according to assigned and unassigned cardiology protocols. JMCGH Emergency Department is always open 24/7 and the West Tennessee Heart and Vascular Center has both a STEMI, as well as a General Cardiology on call physician 24/7.

PROCEDURE:

1. Once the physician at a referring facility feels the need to transfer the patient for suspected STEMI and higher level of Cardiology care, that facility will contact the JMCGH Call Center at 1-800-601-0830 (Physician Referral Line)
2. The Call Center will be prompted to ask the referring facility the following questions:
 - ✓ Do they have ST Elevation?
 - ✓ Do they have a Cardiologist?
 - ✓ Fax EKG to 731-541-9595
3. The Call Center will inform the transferring ED to "Prepare the patient for transport while she gets IC and EDP on phone conference to discuss Reperfusion strategy".
4. The Call Center will then contact JMCGH IC and ED physician to inform them of STEMI transfer and if Assigned or Unassigned.
5. The Call Center will confirm that JMCGH EDP has a copy of EKG.
6. The Call Center will then connect 4-way call including IC, referring EDP, and JMCGH EDP to discuss Initial Reperfusion Strategy.
7. The IC/ED physician will accept the patient and follow the attached algorithms.

8. The Call Center contacts PBX Operator to activate JMCGH Cardiac Cath Lab.
9. The nurse at the referring facility will call patient report to Call Center.

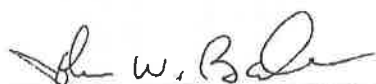
EDUCATION: Explanation and Education provided to referring facilities of the appropriate transfer process; ER physicians, ER staff, and Call Center staff will be educated regarding appropriate transferring process for Auto-Accept Cardiac patients.

DOCUMENTATION: All calls to the call center are recorded. The call between the referring physician, IC and the ED physician will be recorded via the conference lines. The call will be documented by the Call Center nurse in Relay Care transfer software and the patient report information will be documented in First Net – “Coming Attractions” section for use by the accepting facility staff. When the patient arrives at JMCGH Emergency Room, they will be registered and receive an account number so that this information can be attached to the patient’s record. Records from the transferring facility will be scanned into the patient’s chart upon arrival to JMCGH. If EMS performs an ECG within 1 hour of arrival to JMCGH, it may be scanned into the patient’s record as the “initial” EKG. If the EKG was done more than one hour prior to arrival, it will be necessary to repeat the EKG upon arrival to E.D.

RELATED INFORMATION: Refer to algorithms for Auto-Accept for Cardiology – Assigned and Unassigned – General Cardiology, and STEMI/NSTEMI flowcharts.

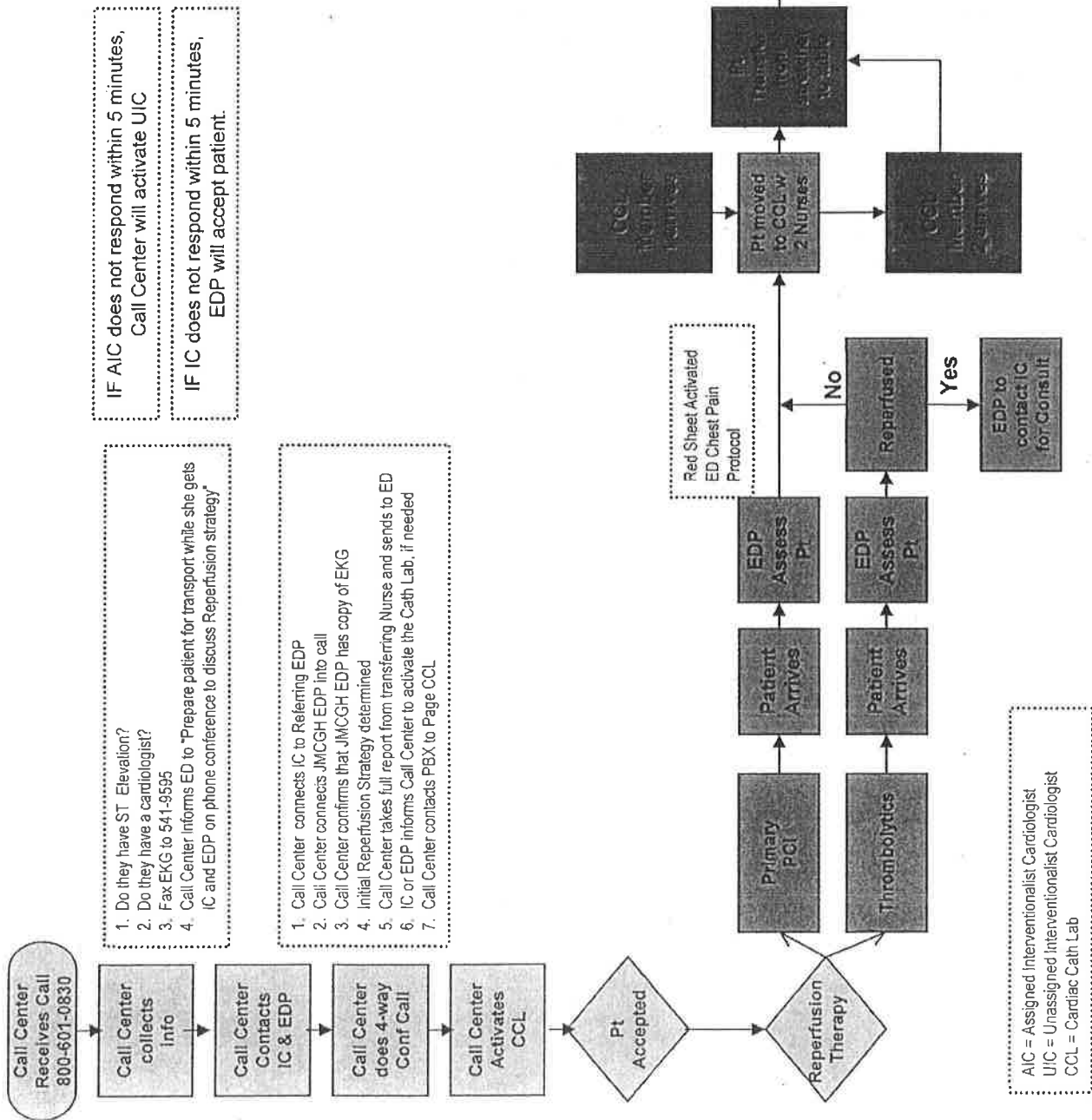
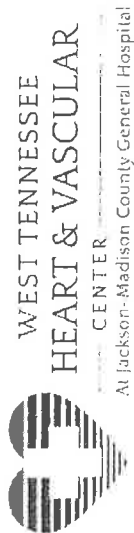


Deann Montchal, Vice-President of Hospital Services



Dr. John Baker, Chest Pain Center Accreditation Medical Director

Auto Accept for Cardiology Patients – Assigned and Unassigned – STEMI Transfer



Please request the Age Group-Specific Historical State Cardiac Catheterization Utilization Rate from the Tennessee Department of Health based upon information from the Hospital Discharge System. Please refer to page 11 of the State Health Plan Certificate of Need Standards and Criteria for Cardiac Catheterization Services that defines "Age Group-Specific Historical State Utilization Rate" for the purpose of defining need in the proposed service area.

Please note: As indicated in the State Health plan, the age group-specific historical state utilization rate will be calculated separately for diagnostic and therapeutic catheterization cases and will be a running average. The Department of Health shall maintain the ongoing age group-specific historical state utilization rate to avoid breaches of patient confidentiality.

The applicant made numerous unsuccessful attempts to obtain this data from the Department of Health, and apparently such data is not maintained and/or not available. This issue is affirmatively addressed by the applicant on page 22 of the application.

These efforts began in approximately November 2013 and continued through February of 2014 without resolution. When it was apparent the data was not available, the applicant incorporated an alternative approach to determine need that relied on actual transfer data for cardiac reasons. In addition, DRMC further validated this approach when comparing the calculated service area utilization rate to that of the nation. With a lower utilization rate for therapeutic cardiac catheterization procedures in the area (as compared to the nation), the applicant was confident that the approach used was a conservative one. The methodology used by the applicant is reasonable and logical, and takes into account the service area utilization rate compared to the national utilization rate. The only data set missing, because it is not available, is the age-specific utilization rates. Please see pages 22-24 of the application.

Please clarify how the applicant came to the conclusion that 25% of patients transferred from DRMC received a therapeutic catheterization procedure.

Through an evaluation of national discharge data sets from the Agency for Healthcare Research and Quality ("AHRQ") coupled with an understanding of the potential treatment options this transported cardiac patient population may receive, the applicant estimated that approximately 47% of this EMS transported patient group would consist of complex patients managed medically, 10% to open heart surgery, 33% to PCI, and 10% to another procedure. In an effort to take a more conservative approach, DRMC reduced this conversion rate to PCI from 33% to just 25% of this patient group. The 25% is just an estimate, but the applicant believes it is a reliable, conservative estimate.

9. Section C. 1. Need (Specific Criteria - Cardiac Catheterization) Item 9

In table 10 there is a slight calculation error in Year Two "Total Adult Cardiac Cath Lab Cases". Please revise.

A revised Table 10 as part of Replacement page 26 is attached following this response.

10. Section C. 1. Need (Specific Criteria - Cardiac Catheterization) Item 15

The applicant states a formal transfer agreement with an open heart tertiary center will be maintained. Please clarify the name of the open heart tertiary center the applicant is referring.

Vanderbilt University Medical Center
St. Francis Hospital

An Agreement with Jackson Madison County General Hospital is not necessary (see response to Supplemental Question 8).

11. Section C. 1. Need (Specific Criteria - Cardiac Catheterization) Item 16

Please clarify if the existing two DRMC cardiologists meet the minimum physician requirements to initiate the proposed therapeutic cardiac catheterization program.

There are two categories of cardiologists involved in this project: (1) the invasive cardiologists who are performing the diagnostic procedures now at DRMC, and (2) the interventional cardiologists who will perform the interventional PCI procedures if this application is approved.

The invasive cardiologists now on staff and performing diagnostic procedures will be maintained under the current arrangements and will continue performing diagnostic procedures even if and when this application is approved. The existing two DRMC cardiologists do not meet the minimum physician requirements, because they are invasive cardiologists and do not and will not perform the interventional procedures.

The interventional cardiologists will be recruited and brought onto the medical staff to perform the interventional procedures if and when this application is approved. Several interventional Cardiologists that meet these guidelines have expressed an interest in working at a new PCI program at DRMC, but without the approval to proceed it is deemed premature at this point to contract with these eligible physicians. DRMC intends to maintain compliance regarding the minimum physician requirements of at least two (2) interventional cardiologists with at least one having performed an average of 75 therapeutic cardiac procedures over the most recent five year period. DRMC affirms the cardiologists that will be providing therapeutic cardiac service will be either board eligible or board certified in cardiology and other relevant cardiac subspecialties.

Please provide the following information for the two existing DRMC cardiologists: 1) estimated number of diagnostic cardiac procedures conducted for the past five (5) years, and 2) the estimated number of therapeutic cardiac procedures conducted for the past five (5) years.

<i>Dr. Geha</i>	Pts. Diagnostic CC Only	Procedures Diagnostic CC Only	Total Pts.	Total Procedures*
2011	52	328	59	346
2012	160	1006	196	1100
2013	177	1042	199	1095
2014 (thru Feb.)	20	91	23	97

<i>Dr. Shahbaz</i>	Pts. Diagnostic CC Only	Procedures Diagnostic CC Only	Total Pts.	Total Procedures
2011				
2012				
2013	41	172	48	194
2014 (thru Feb.)	13	61	15	65

*Total Procedures include cardiac procedures that are not catheterizations, for example, cardioversions and transesophageal echocardiogram.

Please provide the names and credentials (i.e., curriculum vitae's and Board Certificates) for the physicians on the hospital's medical staff who will be performing these procedures. Please note those physicians who are board certified invasive and/or interventional cardiologists.

There are no physicians on the hospital staff who will be performing the interventional procedures. There are two categories of cardiologists involved in this project: (1) the invasive cardiologists who are performing the diagnostic procedures now at DRMC, and (2) the interventional cardiologists who will perform the interventional PCI procedures if this application is approved.

The invasive cardiologists now on staff and performing diagnostic procedures will be maintained under the current arrangements and will continue performing diagnostic procedures even if and when this application is approved. The existing two DRMC cardiologists do not meet the minimum physician requirements, because they are invasive cardiologists and do not and will not perform the interventional procedures.

The interventional cardiologists will be recruited and brought onto the medical staff to perform the interventional procedures if and when this application is approved. Several interventional Cardiologists that meet these guidelines have expressed an interest in working at a new PCI program at DRMC, but without the approval to proceed it is deemed premature at this point to contract with these eligible physicians. DRMC intends to maintain compliance regarding the minimum physician requirements of at least two (2) interventional cardiologists with at least one having performed an average of 75 therapeutic cardiac procedures over the most recent five year period. DRMC affirms the cardiologists that will be providing therapeutic cardiac service will be either board eligible or board certified in cardiology and other relevant cardiac subspecialties.

12. Section C. 1. Need (Specific Criteria - Cardiac Catheterization) Item 18

The applicant states a cardiologist departed from DRMC in 2012. Please clarify if the cardiologist left because of the lack of therapeutic cardiac catheterization capabilities at DRMC.

No, that was not the reason for the departure of the cardiologist.

13. Section C, Need, Item 4.A.

Your response to this item is noted. Using population data from the Department of Health, enrollee data from the Bureau of TennCare, and demographic information from the US

Census Bureau, please complete the following table and include data for each county in your proposed service area.

A table with the requested data appears below:

<i>Variable</i>	<i>Crockett</i>	<i>Dyer</i>	<i>Gibson</i>	<i>Lake</i>	<i>Lauderdale</i>	<i>Obion</i>	<i>Service Area (Counties based in TN)</i>	<i>TN</i>
<i>Current Year (2014), Age 65+*</i>	2,550	6,273	8,788	1,134	3,834	5,922	28,501	981,984
<i>Projected Year (2016), Age 65+*</i>	2,602	6,550	8,991	1,183	5,190	6,101	30,617	1,042,071
<i>Age 65+, % Change</i>	2.0%	4.4%	2.3%	4.3%	35.4%	3.0%	7.4%	6.1%
<i>Age 65+, % Total (PY)</i>	17.8%	17.1%	17.4%	12.3%	19.1%	19.5%	17.7%	15.5%
<i>CY, Total Population*</i>	14,596	38,218	51,102	9,732	27,341	31,453	172,442	6,588,698
<i>PY, Total Population*</i>	14,620	38,301	51,695	9,605	27,188	31,297	172,706	6,710,579
<i>Total Pop. % Change</i>	0.2%	0.2%	1.2%	-1.3%	-0.6%	-0.5%	0.2%	1.8%
<i>TennCare Enrollees**</i>	3,449	9,161	11,221	1,941	6,976	6,514	39,263	1,194,860
<i>TennCare Enrollees as a % of Total Population(CY)</i>	23.6%	24.0%	22.0%	19.9%	25.5%	20.7%	22.8%	18.1%
<i>Median Age***</i>	39.6	39.3	39.9	38.3	36.4	41.1	Not Avail.	38
<i>Median Household Income****</i>	\$37,601	\$38,167	\$36,981	\$26,212	\$32,987	\$40,516	Not Avail.	\$44,140
<i>Population % Below Poverty Level****</i>	19.2%	19.2%	18.6%	30.3%	26.1%	17.1%	Not Avail.	17.3%

*Source: Tennessee Department of Health Population Projections, 2010-2020

**Source: TennCare 2013 Enrollment Data. Data derived from "Midmonth Report for November 2013"

***Source: U.S. Census Bureau: 2010 Demographic Profile Data

****Source: U.S. Census Bureau: State and County QuickFacts. Data representative of 2008-2012

Variances exist between the median household income and percent of population below the poverty level figures reported in this response and the CON application due to differing sources for data. However, in both cases, all counties in the DRMC service area are report median household incomes that are below the state average. In this data set, 5 of 6 service area counties exceed the state's percentage of population that is below the poverty level. This data suggests DRMC serves a population that is older and at lower income levels than the state average.

14. Section C, Need, Item 5

Table 17 on page 36 is noted. However, there appears to be calculation errors in the grand total of the chart. Please revise.

A revised Table 17 is attached following this response.

Table 17 – Cardiac Utilization Trends 2010-2012, Dyersburg Regional Medical Center Proposed Service Area¹

Hospitals in Dyersburg Regional Medical Center's Proposed Service Area	Cardiac Utilization Trends (volume of patients)		
	2010	2011	2012
Baptist - Lauderdale	0	0	0
Diagnostic Cardiac Catheterization ("Cath")	0	0	0
Percutaneous Transluminal Coronary Angioplasty ("PTCA")	0	0	0
Stents	0	0	0
Baptist - Union City	54	37	31
Cath	54	37	31
PTCA	0	0	0
Stents	0	0	0
Dyersburg Regional Medical Center	376	326	275
Cath	376	326	275
PTCA	0	0	0
Stents	0	0	0
Gibson General Hospital	0	0	0
Cath	0	0	0
PTCA	0	0	0
Stents	0	0	0
Humboldt General Hospital	0	0	0
Cath	0	0	0
PTCA	0	0	0
Stents	0	0	0
Milan General Hospital	0	0	0
Cath	0	0	0
PTCA	0	0	0
Stents	0	0	0
Grand Total	430	363	306

¹ Data Sources: Tennessee Department of Health, Joint Annual Report of Hospitals 2010-2012; DRMC internal discharge data for DRMC volume to reflect patients rather than procedures

15. Section C, Need, Item 6

Table 21 on page 39 is noted. However, there appears to be slight calculation errors in the DRMC PCI volume for Year 1 and Year 2. If needed, please revise.

Table 22 is noted. However, there appears to be a slight calculation error in the number of projected total adult cardiac cath lab cases in Year 2. If needed, please revise.

Revised Table 21 and revised Table 22 are attached following this response.

Table 21 – DRMC PCI Volume Projections

	2013		Year 1 (2015)	Year 2 (2016)	Year 3 (2017)
PCI Volume in DRMC Service Area	386		392	395	398
Projected DRMC Market Share*	0%		33.33%	41.67%	50.00%
DRMC PCI Volume	0		131	165	199

*Projected market share is displayed to reflect just two decimal points although the actual figure continues beyond this point.

Table 22 – DRMC's Historic and Projected Cardiac Catheterization Volumes and Lab Utilization

Dyersburg Regional Medical Center Utilization Statistics	HISTORIC			PROJECTED	
Service	2011	2012	2013	Year 1	Year 2
Diagnostic Cardiac Cath	376	322	218	393	494
Therapeutic Cardiac Cath	0	0	0	131	165
Total Adult Cardiac Cath Lab Cases	376	322	218	524	659
DRMC Cardiac Cath Labs	1	1	1	1	1
Volume of Weighted Cases Available (2,000 per lab)	2,000	2,000	2,000	2,000	2,000
DRMC Weighted Cases	376	322	218	655	824
Lab Utilization	18.8%	16.1%	10.9%	32.8%	41.2%

16. Section C, (Economic Feasibility) Item 1. Project Costs Chart

The moveable equipment cost of \$100,000 is noted. However, please list all equipment over \$50,000.

The equipment projected to cost over \$50,000 that is required to advance from diagnostic to therapeutic cardiac catheterization capabilities at DRMC would include an Intravascular Ultrasound System ("IVUS") and a Fractional Flow Reserve ("FFR") System. This equipment is recommended as part of the ACC/AHA/SCA&I guidelines, and are tools that aid in determining the clinical necessity of therapeutic cardiac catheterization. The cost of IVUS and an FFR System were priced as a combination unit, and the estimated cost is \$100,000. A revised Project Cost Chart listing the equipment is attached following this response.

17. Section C., Economic Feasibility, Item 4 (Historical and Projected Data Charts)

The HSDA is utilizing more detailed Historical and Projected Data Charts. Please complete the revised Historical and Projected Data Charts provided as an attachment. Please note that "Management Fees to Affiliates" should include management fees paid by agreement to the parent company, another subsidiary of the parent company, or a third party with common ownership as the applicant entity. "Management Fees to Non-Affiliates" should also include any management fees paid by agreement to third party entities not having common ownership with the applicant. Management fees should not include expense allocations for support services, e.g., finance, human resources, information technology, legal, managed care, planning marketing, quality assurance, etc. that have been consolidated/centralized for the subsidiaries of a parent company.

A revised Historical Data Chart and a Revised Projected Data Chart are attached following this response.

Please clarify if the projected data chart represents patients for the proposed therapeutic cardiac catheterization service, or the total patients for both diagnostic and therapeutic services.

The Projected Data Chart represents patients for the proposed therapeutic cardiac catheterization service, as well as just the incremental diagnostic cardiac catheterization volume that is projected as a result of initiating a therapeutic cardiac catheterization program at DRMC.

Please clarify why the Projected Data Chart reflects 333 patients in Year One and 467 patients in Year Two; while table 22 on page 40 of the application reflects 524 in Year One, and 658 in Year Two.

The Projected Data Chart is inclusive of the incremental patient volumes that are projected to result from an expansion in capabilities at DRMC to include therapeutic cardiac catheterization. Whereas, Table 22 on page 40 of the application is intended to denote the historical and projected utilization of the existing cardiac catheterization lab at DRMC. For an understanding of lab utilization, it is important to include the total volumes (existing plus new) of patients that would be cared for in the lab space. Therefore, the additional volumes included in Table 22 are inclusive of existing diagnostic cardiac catheterization, and projected new diagnostic and therapeutic patient volumes.

18. Section C. (Economic Feasibility) Item. 6. A Charges

On page 47 the applicant states the anticipated revenue from the proposed project will total \$2,610,350 in Year One and \$3,500,268 in Year Two. Please revise the response to specify "Net Operating Revenue" will total \$2,610,350 in Year One and \$3,500,268 in Year Two and submit a replacement page.

The requested revision is reflected on replacement page 47, attached following this response.

The applicant states the cost of emergency transport would significantly decrease with the lack of need to transport patients outside the area for care. If possible, what would be the estimated transportation cost savings to the health care system if this proposed service is approved?

The costs associated with emergency transport directly relate to a few factors, with one being the distance that the vehicle or air transport would need to travel. With an expansion of capabilities at DRMC to include therapeutic cardiac catheterization, DRMC would be in a position to care for more complex patients, such as those experiencing a heart attack. Rather than have to transfer these patients to a provider located over 47 miles away into another county, the patient could receive care at DRMC. This elimination of a need for emergent transfer undoubtedly will reduce the cost to the health care system in west Tennessee. The total impact on the cost of the healthcare system may be difficult to determine, as the analysis would be multi-factorial and include a number of assumptions. With ground transfer costs exceeding \$1,600 and air transfer costs exceeding \$30,500 it is clear that the impact, however, of the initiating PCI services at DRMC will be significant (see table below). It can reasonably be assumed that the cost of transfer via either modality will increase as the distance to the destination hospital from DRMC increases.

Destination Hospital	Address	Ground Miles from DRMC	Ground Transfer Cost	Approx. Nautical Miles from DRMC	Air Transfer Cost
Regional Hospital of Jackson	367 Hospital Blvd Jackson, TN 38305	47.8 miles	\$1,657	38.8 miles	\$30,513
Jackson-Madison County General Hospital	620 Skyline Drive Jackson, TN 38301	48.4 miles	\$1,666	41.9 miles	\$31,775

19. Section C. (Economic Feasibility) Item. 9

Table 24 is noted. However, it is unclear how the estimated Year One revenue and % of total project revenue were calculated for State and Federal Revenue programs. Please clarify.

The payor mix for cardiovascular patients cared for at DRMC includes over 80% that are attributable to State and Federal revenue programs (Medicare and Medicaid/TennCare). Additionally, approximately 3% of the payor mix is attributable to a Medically Indigent (uninsured/self-pay) patient population. When projecting net operating revenue for this project, DRMC applied its actual experience in regards to reimbursement to account for the projected incremental diagnostic cardiac catheterization patient volumes. Without having performed therapeutic cardiac catheterization procedures at DRMC, the applicant applied the anticipated Medicare case rates for projected Medicare patient volumes and the historical percent of payment relative to Medicare case rates for the other projected patient volumes by payor. As expected, reimbursement for a specific procedure varies by payor. In the case of the Medicaid/TennCare patient population, DRMC typically receives lower reimbursement rates for procedures when compared with commercial payors and Medicare. Therefore, when applying the expected case rates by payor, the actual percent of project revenues for the Medicaid patient population is lower than the actual percent of the expected payor mix. In this case, the cardiovascular patient payor mix is expected to include 74% Medicare, 8% Medicaid/TennCare, and 3% Medically Indigent (uninsured/self-pay), while the percent of project revenues is 75% Medicare, 3% Medicaid/TennCare, and 3% Medically Indigent.

20. Section C. (Contribution to Orderly Development) Item 1

Attachment C, (III (1) Contractual Agreements is noted. However, AMISUB (SFH) Inc. d/b/a St. Francis Hospital is not included. Please include in the attachment and resubmit.

A revised Attachment C, III, (1) Contractual Agreements is attached following this response.

Dyersburg Regional Medical Center Health Care Contracts

Ahmad Al-Hamda, MD	On Call Coverage
Apex Cardiology	On Call Coverage
Brook Adams, MD	On Call Coverage
Oakwood Community Living Center	Patient Transfer
Duckworth Pathology Group	Pathology
Duckworth Pathology Group	Pathology
Dyersburg Manor Nursing & Rehab Center	Under Arrangements Skilled Nursing Facility
EmCare Physician Services, Inc.	Surgery
Family Care, PC	Cardiology
G Bradford Wright MD	On Call Coverage
James Naifeh, MD	On Call Coverage
Keith Nord MD	On Call Coverage
The Bridge at Ridgely	Patient Transfer
Memphis Hearing Aid & Audiological	Audiology
Mid South Transplant Foundation, Inc.	Organ Procurement or Harvesting
Monroe Carrell Jr Childrens Hospital at Vanderbilt	Patient Transfer
Reelfoot Manor Nursing Home	Patient Transfer
Regional Hospital of Jackson	Patient Transfer
St. Francis Hospital	Patient Transfer
The Highlands of Dyersburg	Patient Transfer
Timothy D Sweo MD	On Call Coverage
Vanderbilt University Medical Center	Patient Transfer
Virtual Radiological Professionals Of Minnesota PA	Radiology-Imaging
William Matthew Tosh DO	On Call Coverage

21. Section C. (Contribution to Orderly Development) Item 3

Please confirm the applicant will add a .5 FTE cardiology radiology technician and 1.0 FTE registered nurse if this proposed project is approved.

That is correct. DRMC has a complement of personnel in place to manage the existing diagnostic cardiac catheterization lab. With approval of this application, DRMC will need to add additional personnel to ensure the hospital has an adequate number of nurses and radiology technicians to continue to provide services Monday – Friday from 7am to 4pm, but now also to care for an emergent patient population that can present to the hospital at any time. The additional 1.5 FTEs coupled with the existing cardiac catheterization lab staff is expected to meet the need to manage the daily operations of the lab and account for an on-call team for non-operating times. DRMC's financial projections for this project, included in the Projected Data Chart, include the additional salaries required for this on-call time.

22. Proof of Publication

Please submit a copy of the full page of the newspaper in which the notice of intent appeared with the mast and dateline intact or submit a publication affidavit which is supplied by the newspaper as proof of the publication of the letter of intent.

A Publisher's Affidavit is attached following this response.

STATE GAZETTE

294 US Highway 51 Bypass N.
Dyersburg, TN 38024
731-285-4091
Fax: 731-285-9747

I, Jina Jeffries, business manager of the State Gazette, a newspaper published at Dyersburg, Tennessee, hereby certify that the annexed advertisement has been published _____ consecutive/non-consecutive days/weeks in said paper on the following dates: 3/9/14 and that the fee of \$ 169.06 has/has not been paid.

Jina Jeffries

This 12th day of March, 2014

Shelia Rouse, Notary Public

Commission expires: February 14, 2018



DEADLINES for Display Ads

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Wednesday	Monday 4 pm
Thursday	Tuesday 4 pm
Friday	Wednesday 4 pm
Saturday	Thursday 4 pm

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LEG 4-03-250

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Dyersburg, Tennessee
731-286-4114

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March 25, 2014
10:35am

AFFIDAVIT

STATE OF TENNESSEE

COUNTY OF DYER

NAME OF FACILITY: Dyersburg Regional Medical Center

I, Ben Youree, after first being duly sworn, state under oath that I am the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete.


NameCEO
Title

Sworn to and subscribed before me this the 20th day of March, 2014, a Notary Public in and for Dyer County Tennessee.


Notary PublicMy Commission Expires: 1-18-16

COPY SUPPLEMENTAL-2

Dyersburg Regional Med.

CN1403-007

SECOND SUPPLEMENTAL RESPONSES

CERTIFICATE OF NEED APPLICATION

FOR

DYERSBURG REGIONAL MEDICAL CENTER

Project No. CN1403-007

**Expansion Of Existing Cardiac Catheterization Service
to Include Interventional Cardiac Catheterization**

Dyer County, Tennessee

March 27, 2014

Contact Person:

**Jerry W. Taylor, Esq.
Stites & Harbison, PLLC
401 Commerce Street, Suite 800
Nashville, Tennessee 37219
615-782-2228**

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SUPPLEMENTAL

1. Section C, Need, Item 4.A.

Your response to this item is noted. Please resubmit the following table using the year 2018 for the projected year (PY) rather than 2016 as previously submitted in the first supplemental.

A revised table reflecting 2018 as the PY is attached following this response.

Variable	Crockett	Dyer	Gibson	Lake	Lauderdale	Obion	Service Area (Counties based in TN)	TN
Current Year (2014), Age 65+*	2,550	6,273	8,788	1,134	3,834	5,922	28,501	981,984
Projected Year (2018), Age 65+*	2,644	6,801	9,211	1,218	4,194	6,235	30,303	1,102,413
Age 65+, % Change	3.7%	8.4%	4.8%	7.4%	9.4%	5.3%	6.3%	12.3%
Age 65+, % Total (PY)	18.1%	17.8%	17.8%	12.7%	15.4%	19.9%	17.5%	16.4%
CY, Total Population*	14,596	38,218	51,102	9,732	27,341	31,453	172,442	6,588,698
PY, Total Population*	14,620	38,301	51,695	9,605	27,188	31,297	172,706	6,710,579
Total Pop. % Change	0.2%	0.2%	1.2%	-1.3%	-0.6%	-0.5%	0.2%	1.8%
TennCare Enrollees**	3,449	9,161	11,221	1,941	6,976	6,514	39,263	1,194,860
TennCare Enrollees as a % of Total Population(CY)	23.6%	24.0%	22.0%	19.9%	25.5%	20.7%	22.8%	18.1%
Median Age***	39.6	39.3	39.9	38.3	36.4	41.1	Not Avail.	38
Median Household Income****	\$37,601	\$38,167	\$36,981	\$26,212	\$32,987	\$40,516	Not Avail.	\$44,140
Population % Below Poverty Level****	19.2%	19.2%	18.6%	30.3%	26.1%	17.1%	Not Avail.	17.3%

2. Section C., Economic Feasibility, Item 4 (Historical and Projected Data Charts)

The revised Historical and Projected Data Charts with management fees are noted. Please recalculate the operating expense section for the years 2011, 2012, and 2013 of the Historical Data Chart and resubmit.

A revised Historical Data Chart with recalculated operating expense entries is attached following this response.

Please clarify why the Projected Data Chart for the proposed project does not include an allocation for management fees. If needed, please submit a revised Projected Data Chart with management fees included.

The management fees cover all support services provided to each member hospital by CHS on a hospital-wide basis, and are not allocated by department or service line. Therefore, there is no practical way to allocate a portion of the fees to the cardiac catheterization services.

3. Section C. (Economic Feasibility) Item. 9

The response of how the estimated Year One revenue and % of total project revenue were calculated for State and Federal Revenue programs is noted. However, it remains unclear what amount from the projected data chart the applicant used to determine the percentage of total project revenue for Medicaid/TennCare and Medicare in Year One. HSDA staff calculates the percentage of gross charges in Year One as follows:

- Medicaid/TennCare: \$603,078 or 3% gross operating revenue
- Medicare: \$15,075,947 or 75% of gross operating revenue
- Indigent: \$603,078 or 3% of gross operating revenue

Please verify.

The applicant verifies the above amounts are correct based on projected patient mix as a percentage of projected gross operating revenue, with the exception that our calculation shows the projected Medicare revenue as \$15,076,947, or 75% of gross operating revenue.

4. Proof of Publication

The publication affidavit which is supplied by the newspaper as proof of the publication of the letter of intent and a copy of the publication is noted. However, please provide an enlarged copy of the publication with a larger legible font.

An enlarged copy of the publication is attached following this response.

CLASSIFIED

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Legals

LEGAL 03-2506

NOTIFICATION OF INTENT TO APPLY FOR A Certificate of Need

This is to provide official notice to the Health Services and Development Agency and all interested parties, in accordance with T.C.A. § 68-11-1601 et seq., and the Rules of the Health Services and Development Agency, that: Dyersburg Regional Medical Center owned and managed by Dyersburg Hospital Corporation intends to file an application for a Certificate of Need for the expansion of its cardiac catheterization services, currently limited to diagnostic procedures, to include interventional (therapeutic) cardiac catheterization procedures and the initiation of such services. Dyersburg Regional Medical Center is located at 400 Tickle Street, Dyersburg, Dyer County, Tennessee. Dyersburg Regional Medical Center is licensed as a general hospital by the Tennessee Board for Licensing Healthcare Facilities. The licensed bed complement of the hospital will not be affected by this proposal. No major medical equipment is involved in this proposal. The estimated project cost is \$367,753.00.

The anticipated date of filing the application is March 14, 2014.

The contact person for this project is Jerry W. Taylor, Attorney, who may be reached at Stiles and Harrison, PLLC, 461 Commerce Street, Suite 800, Nashville, Tennessee, 37219, 615-782-2228.

Upon written request by interested parties, a local Fact-Finding public hearing shall be conducted. Written requests for hearing should be sent to:

Health Services and Development
Agency
Andrew Jackson Building, Ninth
Floor
502 Deaderick Street
Nashville, TN 37243

Pursuant to T.C.A. § 68-11-1607(b)(1): (A) Any health care institution wishing to oppose a Certificate of Need application must file a written notice with the Health Services and Development Agency no later than fifteen (15) days before the next scheduled Health Services and Development Agency meeting at which the application is originally scheduled; and (B) Any other person wishing to oppose the application must file a written objection with the Health Services and Development Agency at or prior to the consideration of the application by the Agency.

AFFIDAVIT

MAR 27 14 PM 2:05
SUPPLEMENTAL

STATE OF TENNESSEE

COUNTY OF DAVIDSON


NAME OF FACILITY: Dyersburg Regional Medical Center

I, Jerry W. Taylor, after first being duly sworn, state under oath that I am the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete.


Name

Title

Sworn to and subscribed before me this the 27th day of March, 2014, a Notary Public in and for Dyer County Tennessee.


Notary Public

My Commission Expires: 3-7-2017



**Additional
Information
SUPPLEMENTAL-#2a
-Copy-**

**Dyersburg Regional Medical
Center**

CN1403-007

June 23, 2014

12:30 pm

SunTrust Plaza
401 Commerce Street
Suite 800
Nashville, TN 37219
(615) 782-2200
(615) 782-2371 Fax
www.stites.com

Jerry W. Taylor
(615) 782-2228
(615) 742-0703 FAX
jerry.taylor@stites.com

June 23, 2014

Phillip Earhart
Health Services Development Examiner
Health Services & Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, TN 37243

Re: Dyersburg Regional Medical Center
CN1403-007

Dear Phillip:

You had asked about an apparent discrepancy between the projected number of cases for Year 1 and Year 2 in Table 10 on page R-26, and the number of projected cases in the Projected Data Chart (revised PDC is in the supplemental Responses but is not page-numbered).

As we discussed, the projected cases in Table 10 reflect all projected volume, both diagnostic and therapeutic. The projected cases in the PDC are the incremental volume only. This was intended to reflect the revenues and expenditures for this project only, and not the existing (diagnostic) volume.

However, this is further complicated by the fact that when the PDC was prepared, the 2013 number of diagnostic cases was an annualized number because at the time it was originally created (approximately November of 2013) the actual number of diagnostic cases for 2013 was not known. So, if you take the 524 total projected cases for Year 1 in Table 10 and subtract the then-estimated existing volume from 2013 (192 annualized cases at the time it was prepared), the incremental volume for Year 1 is 332 (apparently somehow rounded to 333). The same math holds true for Year 2. So, these are the incremental volumes reflected on that PDC (333 in Year 1, 467 in Year 2).

But by the time Table 10 was prepared, the actual number of diagnostic cases performed at DRMC in 2013 was known (218, which is reflected for 2013 in that Table). So there is a difference of 27 cases and to be totally accurate the PDC should show 27 fewer incremental cases for each projection year. During this look back it was also discovered that there were relatively minor discrepancies in the number of historical diagnostic cath cases actually performed at DRMC in 2012 and 2011, and those which were originally reflected in Table 10.

June 23, 2014**12:30 pm**

STITES & HARBISON PLLC
ATTORNEYS

Phillip Earhart
June 23, 2014
Page 2

Submitted herewith are Replacement Pages for all pages affected by the corrections, and a Replacement Projected Data Chart accurately reflecting the projected incremental cases and the revenues and expenditures based on the same.

During the look back it was also discovered there were errors in the Joint Annual Reports for 2013 and 2012. The volumes of diagnostic caths were erroneously reported by number of cases (patients) rather than procedures as called for by the report form. Amended JARs for 2013 and 2012 have been submitted to Lonnie Mathews at the Division of Health Statistics.

Thank you for bringing the discrepancy to our attention, and for the opportunity to correct the same. Please let me know if you have any questions.

Sincerely yours,

STITES & HARBISON PLLC



Jerry W. Taylor

cc: Vicki Lake, West Tennessee Healthcare
vicki.lake@wth.org

Dan Elrod, Esq.
dan.elrod@butlersnow.com



Jackson-Madison County General Hospital™

An affiliate of West Tennessee Healthcare

620 Skyline Drive • Jackson, Tennessee 38301 • 731-541-5000 • www.wth.org

June 11, 2014

Ms. Melanie Hill, Executive Director
State of Tennessee Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, Tennessee 37243

RE: Dyersburg Regional Medical Center CN1403-007
Opposition by Jackson-Madison County General Hospital

Dear Ms. Hill,

This letter serves as notification that Jackson-Madison County General Hospital is in opposition of CN1403-007 submitted by Dyersburg Regional Medical Center for the initiation of interventional (therapeutic) cardiac catheterization services. We believe there is not an established need for this project; that it is not economically feasible, and does not contribute to the orderly development of healthcare in rural West Tennessee.

We will have representatives at the Health Services and Development Agency meeting on June 25th.

Sincerely,

Victoria S. Lake
Director Market Research and Community Development

Cc: Jerry Taylor, Stites & Harbison, PLLC
Dan Elrod, Butler Snow, LLP
Bobby Arnold, President & CEO, West Tennessee Healthcare
James Ross, Vice President/Chief Operating Officer, West Tennessee Healthcare
Deann Montchal, Vice President, West Tennessee Healthcare



★★★★★★★★★★★★★★★★★★★★ (417) 256-0010 • P.O. Box 768 • West Plains, MO 65775

June 10, 2014

To whom it may concern:

Dyersburg Regional Medical Center (DRMC) recently applied for a Certificate of Need (CON) for interventional cardiology. The area that DRMC serves would benefit highly from having this type of treatment available at their local hospital. Currently, if a patient presents with an ST elevation myocardial infarction (STEMI), they will need to be transported by air or ground to the closest appropriate PCI lab. Transport by air to the closest PCI lab may take up to 20 minutes. If weather is a factor or the closest helicopter is not available, transport by ground may take up to 40 minutes. Having a PCI lab closer to the patients in need of intervention could significantly reduce the amount of time it takes to diagnose, transfer, and definitively treat these patients.

I have personally been a resident in this area my entire life. My immediate and distant family lives here as well. My family has a significant history of heart disease at a rate much higher than the population. Much like everyone, I want my family to have the best care available as close as possible. Currently, without interventional abilities, the best care available could not be given at DRMC, thus they would be taken to Jackson, TN where some of my older family members would not be able to readily visit. Adding interventional abilities at DRMC would decrease the amount of time for definitive care and the amount of damage to the heart created by an infarct. If this were my family, I would not hesitate to bring them to DRMC where they would be closer to home and other family members for emotional support during their recovery; however, without intervention there is not anything that can be done to definitively treat a coronary lesion. My family as well as my fellow residents deserves the best care close to home.

Respectfully,

Bradley J. Woody, NRP, FP-C
Program Director
Air Evac Lifeteam
Dyersburg, TN

City of Dyersburg



425 Court Street West
P.O. Box 1358
731.288.7604

TENNESSEE

JOHN HOLDEN
MAYOR

731-288-7600

jholden@dyersburgtn.gov

June 11, 2014

Melanie M. Hill
Executive Director
Tennessee Health Services and Development Agency
Andrew Jackson Building, Ninth Floor
502 Deaderick Street
Nashville, TN 37243
Re: Dyersburg Regional Medical Center - CN1403-007

Dear Ms. Hill:

My name is John Holden and I have been the Mayor of Dyersburg for the past 8 years. I have spent the majority of my life in this area. As such, over the years I have had many interactions with Dyersburg Regional Medical Center. I have also had several family members and friends who have had experiences with the hospital. With very few exceptions, we have received high quality and efficient care.

One specific example happened very recently. On May 18, my mother was having chest pain and we took her to the emergency department at DRMC. They decided to keep her for observation and while in the hospital her lab values reached a level that the cardiologist wanted to do a diagnostic catheterization. We were extremely satisfied with the care we received, but were disappointed to find out that if the cardiologist found an issue while performing the diagnostic cath that we would have to be shipped all the way to Jackson or Memphis to have the problem fixed.

We wanted to keep our mother in Dyersburg because she has had good experiences here; therefore we are writing this letter to ask that the agency strongly consider approving Dyersburg Regional Medical Center's application for performing interventional cardiac cath. We think this would be of tremendous value to not only Dyersburg and Dyer County, but for surrounding cities and counties as well. After learning this information I took the time to ask around and found that many people in the community share a similar story and would strongly support this service if it were available.

Over the last few weeks I have taken the time to learn more about how the human heart works. My biggest fear is that if my mother, friend, or even myself were to have a heart attack that we would have to be sent all the way to Jackson to receive care. This scares me because all I have read is "time is muscle". To me this is the main reason why Dyersburg Regional Medical Center needs to have the ability to perform these procedures.

I urge you to approve this application. I am confident that it will be supported both locally and regionally, and even more importantly it will save lives.

Sincerely,

A handwritten signature in blue ink that reads "John Holden".

John Holden
Mayor of Dyersburg

JUL 21 4 42 PM '14



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July 1, 2014

Melanie M. Hill, Executive Director
Tennessee Health Services and Development Agency
Andrew Jackson Building, Ninth Floor
502 Deaderick Street
Nashville, TN 37243

Re: Dyersburg Regional Medical Center **CN1403-007**

Dear Ms. Hill:

I am the President of First Citizens National Bank which is headquartered in Dyersburg, TN. I have served in this capacity since 2006. Outside of the few years I spent away at school, I have lived my entire life in this community.

I am writing this letter to request the agency strongly consider approving this application to allow Dyersburg Regional Medical Center the ability to perform Interventional Cardiac Caths. This is a much needed service for our community for several reasons. First, our community members should not have to risk heart muscle by wasting time being transferred to Jackson or Memphis. Second, there is little investment that has to be made to make the existing cath lab operational. Third, this service will keep jobs, revenues, and taxes in our community where they belong.

I have had many interactions with Dyersburg Regional Medical Center over the years including several family members who have been hospitalized both here and in other markets. Our community should feel very lucky to have a hospital as efficient and patient-focused as Dyersburg Regional Medical Center.

I urge you to approve this application helping our local hospital continue to grow and support the patients in Dyersburg and surrounding counties.

Sincerely,

Jeff Agee
President and CEO

Unbelievably Good

June 11, 2014

Tennessee Developmental Agency
And/or
Mr. Ben Youree

Hello, my name is Kim Phipps. I have been a resident of Dyersburg, Tennessee for 36 years.

I would like to share something with you about an experience I had March 5, 2013 at Dyersburg Regional Hospital.

I was scheduled for a routine out-patient thyroid surgery that day. During the surgery, there was apparently some complications that made the surgery last longer than normal. I remember being awake by my Dr. telling me that the surgery showed a good report (no cancer) but that I had a massive heart attack and was being air-lifted to Jackson hospital. Still being under anesthetic, I was somewhat confused about what was going on but I could see that the Dr. and nurses were working very hurriedly for some reason.

I remember bits and pieces about the helicopter ride to Jackson but most information was given to me by my family later.

I understand that there was a 1 hour window in which I had to be transported to Jackson and my heart "fixed" by stent. One hour goes by quickly with all the work that had to be done so it was obvious that everyone was struggling to save my life. I don't know what caused the heart attack and will never know.

Even though I thank God every day for sparing my life, it still comes to me at times: what if there had been no helicopter available on time? What if the Dr.s in Jackson weren't ready for me at the time?

I am very thankful that all the pieces of the puzzle came together as they did. I pray that every patient who comes through Dyersburg hospital has the second chance that I had. Yet if we were to have a cardiac unit as well as trained, experienced Cardiologists in Dyersburg, it would be a much closer experience with less fear maybe.

I have always said that we have such a good hospital and even though no hospital is perfect, we have the ability to improve our hospital and staff and may have the opportunity to save more patients who may not have that one hour time frame to work with as I had.

I will always be grateful to God and thankful for the people in Dyersburg who worked so quickly to save my life. That was a very scary day in my life and one that I hope I never have to repeat.

In closing, even though the memory of the ride lingers in my mind, I'm also thankful for the wonderful people who "took a ride" with me in that helicopter even as terrified as I was. Thank you Air Evac.

God Bless all of you,

A handwritten signature in cursive script that reads "Kim Phipps". The signature is written in dark ink and is positioned above the printed name.

Kim Phipps

Medic One

JUN 18 14 41 05

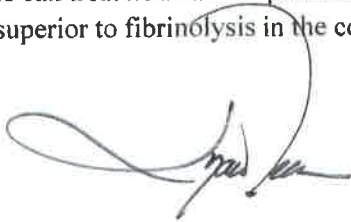
06/10/14

To whom this letter may concern,

The need for Percutaneous Coronary Intervention (PCI) Centers in the rural southern U.S. is evident by the growing number of persons with coronary artery disease. There are @ 600,000 deaths annually attributed to coronary artery disease in the U.S. costing \$108.9 billion dollars per year. Northeast Arkansas and Southeast Missouri lie in this belt that contains the highest rates of annual deaths per 100,000 from coronary artery disease and PCI centers have been proven through research, evidence and science by the American Heart Association to reduce morbidity and mortality as compared to the pharmaceutical use of fibrinolytics in the event of S-T segment elevation MI's or STEMI's also known as heart attacks.

With the ever-changing field of Emergency Medical Services, paramedics are trained to recognize STEMI in the field and are expected to follow the recommendations of the AHA and transport those patients to the nearest appropriate facility that can provide PCI. Many EMS agencies are transmitting the 12 lead ECG to PCI centers and bypassing emergency departments and taking these patients directly to the cath labs for PCI which is saving time and heart muscle.

Simply stated, the closer patients are to PCI Centers and the sooner that person who has had a heart attack can get there may determine whether the person survives the heart attack or not. Rural smaller facilities can treat heart attack patients with "clot-busting" drugs, but the science and evidence shows that PCI is superior to fibrinolysis in the combined end-points of death, stroke and reinfarction.



Shawn Perrin, Nationally Registered paramedic / instructor, AHA Training Center Coordinator,
AHA BLS, ACLS, PALS Regional Faculty

To Whom it may Concern

Past history of heart attack - had
to by-pass hospital less than one
mile from my residence.

Went into Carnory arrest
during transport.

Angioplasty and stent center
in Dyersburg would have benefited
me, so it can be a bigger benefit
for our community.

Phillip Tidwell Sr.

JUN 18 '14 AM 10:59

**CERTIFICATE OF NEED
REVIEWED BY THE DEPARTMENT OF HEALTH
DIVISION OF POLICY, PLANNING AND ASSESSMENT
615-741-1954**

DATE: May 31, 2014

APPLICANT: Dyersburg Regional Medical Center
400 Tickle Street
Dyersburg, Tennessee 38024

CN1403-007

CONTACT PERSON: Jerry W. Taylor, Esquire
401 Commerce Street, Suite 800
Nashville, Tennessee 37219

COST: \$367,763

In accordance with Section 68-11-1608(a) of the Tennessee Health Services and Planning Act of 2002, the Tennessee Department of Health, Division of Policy, Planning, and Assessment, reviewed this certificate of need application for financial impact, TennCare participation, compliance with *Tennessee's State Health Plan*, and verified certain data. Additional clarification or comment relative to the application is provided, as applicable, under the heading "Note to Agency Members."

SUMMARY:

The applicant, Dyersburg Regional Medical Center (DRMC), located at 400 Tickle Street, Dyersburg (Dyer County), Tennessee, seeks Certificate of Need (CON) approval for the expansion of catheterization services, currently limited to diagnostic procedures, to include interventional (therapeutic) cardiac catheterization procedures, and the initiation of such services. The licensed bed complement for the hospital will not be affected and no major medical equipment will be involved in the project.

The project will not involve construction or renovation to initiate therapeutic cardiac catheterization ("Percutaneous Coronary Intervention", or "PCI", or "coronary angioplasty") services, inclusive of primary and elective angioplasty. PCI services will be performed in the existing laboratory.

Dyersburg Regional Medical Center is owned by Dyersburg Hospital Corporation which is wholly owned by Community Health Investment Company, LLC, which is wholly owned by CHS/Community Health Systems, Inc., which is wholly owned by Community Health Systems, Inc.

The total project cost is \$367,763 and will be funded through a commercial loan.

GENERAL CRITERIA FOR CERTIFICATE OF NEED

The applicant responded to all of the general criteria for Certificate of Need as set forth in the document *Tennessee's State Health Plan*.

NEED:

The service area as defined by the applicant includes, Dyer, Lake, and Lauderdale counties, as well as, portions of Crockett, Gibson, and Obion counties. These counties, and portions thereof, are within a 45-mile radius of Dyersburg Regional Medical Center.

The following chart illustrates the total population projections for the six-county service area.

Service Area Population 2014 and 2018

County	2014 Population	2018 Population	% of Increase/ (Decrease)
Crockett	14,596	14,683	0.6%
Dyer	38,218	38,427	0.5%
Gibson	51,102	52,163	2.1%
Lake	9,732	9,468	-2.7%
Lauderdale	27,341	27,125	-0.8%
Obion	31,453	31,222	-0.7%
Total	172,442	173,008	0.4%

Source: *Tennessee Population Projections 2010-2020, June 2013 Revision*, Tennessee Department of Health, Division of Policy, Planning, and Assessment-Office of Health Statistics

DRMC has offered diagnostic cardiac catheterization services, or percutaneous coronary intervention (PCI) and angioplasty, both primary and elective cases since 2009. DRMC's inability to provide a higher level of care, patients that are considered high risk, patients who have a history of coronary artery disease, those that present to the emergency department with an acute myocardial infarction (AMI), and those that require an intervention as determined through diagnostic catheterization are referred and/or transferred to other facilities that offer higher levels of cardiac care not offered at DRMC.

Currently, the closest PCI center to DRMC is 48 miles or 50 minutes away. The American College of Cardiology's established benchmark "door to balloon time" for patients suffering from AMI is 90 minutes or less. The average door to balloon time for transferred patients is 121 minutes. The ability to initiate treatment for AMI patients at the time they present will afford the best possible outcomes. Data from the National Registry of Myocardial Infarction (NORMI) suggests that patients who are transferred for primary PCI are treated 71 minutes later than patients who receive PCI locally. The NORMI registry demonstrates a "door to balloon time" of 2.5 to 3 hours for transferred patients is associated with a 60% increase risk-adjusted mortality compared to patients whose door to balloon time was less than 2 hours.

The applicant projected volumes for expansion of cardiac catheterization by analyzing patient transfer data from hospital records and EMS provider's ground and air transfer in Dyersburg. Through an evaluation of transfer data, the applicant found that 1,021 patients left DRMC for cardiovascular care in 2013, with an average of over 900 cases per year for the last three years. Additionally, 102, 179, and 214 patients from Dyer County in 2011, 2012, and 2013 were transported to providers outside DRMC's service area without receiving care from DRMC.

The Tennessee Department of Health, Division of Policy, Planning, and Assessment used the Cardiac Catheterization Need Formula to calculate the need for therapeutic catheterization in the applicant's service area:

Service Area Hospitals	Number of Cath Labs	Diagnostic Caths	Therapeutic Caths	Total Cardiac Caths
Dyersburg Regional Medical Center	1	761	31	792
Baptist Memorial Hospital-Union City	1	85	0	85
Totals	2	846	31	877

Total Capacity 4,000

Percent of Existing Services to Capacity: 21.9%

Source: Tennessee Department of Health, Division of Policy, Planning, and Assessment

TENNCARE/MEDICARE ACCESS:

DRMC participates in the Medicare and TennCare/Medicaid programs. Currently, the applicant has contracts with United Healthcare Community Plan, BlueCare, and TennCare Select.

The applicant projects year one TennCare/Medicaid revenues of \$83,839 or 3.4% of gross revenues, Medicare revenues of \$1,858,354 or 74.7% of gross revenues, and medically indigent care of \$79,209 or 3.2% of total revenues.

ECONOMIC FACTORS/FINANCIAL FEASIBILITY:

Department of Health, Division of Policy, Planning, and Assessment has reviewed the Project Costs Chart, the Historical Data Chart, and the Projected Data Chart to determine if they are mathematically accurate and the projections are based on the applicant's anticipated level of utilization. The location of these charts may be found in the following specific locations in the Certificate of Need Application or the Supplemental material:

Project Costs Chart: The Project Costs Chart is located on page 41 R of Supplemental 1. The total project cost is estimated to be \$367,763.

Historical Data Chart: The Historical Data Chart is located in Supplemental 2 of the application. The applicant reports 13,109, 12,615, and 11,033 admissions in years 2011, 2012, and 2013 with net operating income of \$8,249,781, \$4,676,217 and \$7,988,585 each year, respectively.

Projected Data Chart: The Projected Data Chart is located in Supplemental 2. The applicant projects 306 patients in year one and 440 patients in year two with net operating income of and \$1,039,170 and \$1,907,022 each year, respectively.

The applicant provided the average charges, deductions, and net charges, and below.

	Year One	Year Two
Average Gross Charge	\$62,599	\$60,786
Average Deduction from Operating Revenue	\$54,470	\$52,893
Average Net Charge	\$8,129	\$7,894

The applicant considered two alternatives to this project: 1) Do nothing or 2) develop an Enhanced Network of Care for PCI. Both alternatives were rejected for reasons discussed by the applicant on pages 49 and 50 of the application.

CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTHCARE:

The applicant provides a list of all providers, managed care organizations, alliances, and/or networks with which the applicant currently has or plans to have contractual and/or working relationships in Supplemental 2.

There are no providers of therapeutic catheterization in the applicant's service area and only one other providers of diagnostic catheterization (Baptist Memorial Hospital-Union City).

The applicant's staff will include 4.0 FTE registered nurses and 2.0 FTE cardiovascular radiology technicians in years one and two of the project.

The applicant provides training and education for registered nurses, licensed practical nurses, radiology technicians, and emergency medical providers through a relationship with Dyersburg State Community College and Jackson State Community College.

DRMC is licensed by the Tennessee Department of Health, Board for Licensing Healthcare Facilities and accredited by Joint Commission.

SPECIFIC CRITERIA FOR CERTIFICATE OF NEED

The applicant responded to all relevant specific criteria for Certificate of Need as set forth in the document *Tennessee's State Health Plan*.

Standards and Criteria for All Cardiac Catheterization Services

Applicants proposing to provide any type of cardiac catheterization services must meet the following minimum standards:

1. **Compliance with Standards:** The Division of Health Planning is working with stakeholders to develop a framework for greater accountability to these Standards and Criteria. Applicants should indicate whether they intend to collaborate with the Division and other stakeholders on this matter.

The applicant complies.

2. **Facility Accreditation:** If the applicant is not required by law to be licensed by the Department of Health, the applicant should provide documentation that the facility is fully accredited or will pursue accreditation by the Joint Commission or another appropriate accrediting authority recognized by the Centers for Medicare and Medicaid Services (CMS).

The applicant is accredited by the Joint Commission and licensed by the Department of Health.

3. **Emergency Transfer Plan:** Applicants for cardiac catheterization services located in a facility without open heart surgery capability should provide a formalized written protocol for immediate and efficient transfer of patients to a nearby open heart surgical facility (within 60 minutes) that is reviewed/tested on a regular (quarterly) basis.

The applicant has transfer agreements with Vanderbilt Medical Center, St. Francis Hospital, Memphis, and the Regional Hospital of Jackson. Additionally, they have a letter of agreement in Supplemental 1 with Methodist Hospital, Memphis.

4. **Quality Control and Monitoring:** Applicants should document a plan to monitor the quality of its cardiac catheterization program, including, but not limited to, program outcomes and efficiency. In addition, the applicant should agree to cooperate with quality enhancement efforts sponsored or endorsed by the State of Tennessee, which may be developed per Policy Recommendation 2.

The applicant will maintain compliance with the most current guidelines published by the American College of Radiology, and the Society for Cardiac Angiography and Interventions and Department of Health licensure.

5. **Data Requirements:** Applicants should agree to provide the Department of Health and/or the Health Services and Development Agency with all reasonably requested information and statistical data related to the operation and provision of services and to report that data in the time and format requested. As a standard of practice, existing data reporting streams will be relied upon and adapted over time to collect all needed information.

The applicant agrees to provide who Department of Health with requested information and statistical data.

6. **Clinical and Physical Environment Guidelines:** Applicants should agree to document ongoing compliance with the latest clinical guidelines of the American College of

Cardiology/Society for Cardiac Angiography and Interventions Clinical Expert Consensus Document on Cardiac Catheterization Laboratory Standards (ACC Guidelines). As of the adoption of these Standards and Criteria, the latest version (2001) may be found online at: <http://www.acc.org/qualityandscience/clinical/consensus/angiography/dirIndex.htm>.

Where providers are not in compliance, they should maintain appropriate documentation stating the reasons for noncompliance and the steps the provider is taking to ensure quality. These guidelines include, but are not limited to, physical facility requirements, staffing, training, quality assurance, patient safety, screening patients for appropriate settings, and linkages with supporting emergency services.

The applicant will participate and submit to the American College of Cardiology's National Cardiovascular Data Registry to monitor its quality and outcomes relative to peer hospitals and agree to cooperate with all efforts related to quality enhancement as sponsored by the State of Tennessee.

7. **Staffing Recruitment and Retention:** The applicant should generally describe how it intends to maintain an adequate staff to operate the proposed service, including, but not limited to, any plans to partner with an existing provider for training and staff sharing.

The applicant will utilize its relationship with other CHS hospitals to access training with existing staff at the hospital caring for cardiac catheterization lab patients.

The applicant will recruit interventional cardiologists and brought on to the Medical staff when the application is approved.

8. **Definition of Need for New Services:** A need likely exists for new or additional cardiac catheterization services in a proposed service area if the average current utilization for all existing and approved providers is equal to or greater than 70% of capacity (i.e., 70% of 2,000 cases) for the proposed service area.

This application is to allow DRMC to advance its service offerings in its current lab and not increase capacity.

9. **Proposed Service Areas with No Existing Service:** In proposed service areas where no existing cardiac catheterization service exists, the applicant must show the data and methodology used to estimate the need and demand for the service.

Projected need and demand will be measured for applicants proposing to provide services to residents of those areas as follows:

Need. The projected need for a service will be demonstrated through need-based epidemiological evidence of the incidence and prevalence of conditions for which diagnostic and/or therapeutic catheterization is appropriate within the proposed service area.

Demand. The projected demand for the service shall be determined by the following formula:

- A. Multiply the age group-specific historical state utilization rate by the number of residents in each age category for each county included in the proposed service area to produce the projected demand for each age category;
- B. Add each age group's projected demand to determine the total projected demand for cardiac catheterization procedures for the entire proposed service area.

The applicant determined need for the expansion to include PCI capabilities by evaluating the service area demographics, understanding the incidence and

mortality rates from heart disease and AMI, and determining the current availability and disease of access to service.

The applicant projected volumes for expansion of cardiac catheterization by analyzing patient transfer data from hospital records and EMS provider's ground and air transfer in Dyersburg. Through an evaluation of transfer data, the applicant found that 1,021 patients left DRMC for cardiovascular care in 2013, with an average of over 900 cases per year for the last three years.

10. **Access:** In light of Rule 0720-4-.01 (1), which lists the factors concerning need on which an application may be evaluated, the HSDA may decide to give special consideration to an applicant:

- a. Who is offering the service in a medically underserved area as designated by the United States Health Resources and Services Administration;

All of the service area counties are MUA with the exception of Gibson.

- b. Who documents that the service area population experiences a prevalence, incidence and/or mortality from heart and cardiovascular diseases or other clinical conditions applicable to cardiac catheterization services that is substantially higher than the State of Tennessee average;

The service area has a high incidence/mortality from heart disease.

- c. Who is a "safety net hospital" as defined by the Bureau of TennCare Essential Access Hospital payment program; or

DRMC is not a safety net hospital.

- d. Who provides a written commitment of intention to contract with at least one TennCare MCO and, if providing adult services, to participate in the Medicare program.

The applicant will serve Medicare and TennCare patients.

Specific Standards and Criteria for Therapeutic Cardiac Catheterization Services

Applicants proposing to provide therapeutic cardiac catheterization services must meet the following minimum standards:

14. **Minimum Volume Standard:** Such applicants should demonstrate that the proposed service utilization will be a minimum of 400 diagnostic and/or therapeutic cardiac catheterization cases per year by its third year of operation. At least 75 of these cases per year should include a therapeutic cardiac catheterization procedure.

The applicant did not provide data for its third year of operation.

Annual volume shall be measured based upon a two year average which shall begin at the conclusion of the applicant's first year of operation. Only cases including diagnostic and therapeutic cardiac catheterization procedures as defined by these Standards and Criteria shall count towards meeting this minimum volume standard.

The applicant complies.

15. **Open Heart Surgery Availability:** Acute care facilities proposing to offer adult therapeutic cardiac catheterization services shall not be required to maintain an on-site open heart surgery program. Applicants without on-site open heart surgery should follow the most recent American College of Cardiology/American Heart Association/Society for Cardiac Angiography and Interventions Practice Guideline Update for Percutaneous Coronary Intervention (ACC/AHA/SCAI Guidelines). As of the adoption of these Standards and Criteria, the latest version of this document (2007) may be found online at: <http://circ.ahajournals.org/cgi/reprint/CIRCULATIONAHA.107.185159>

Therapeutic procedures should not be performed in freestanding cardiac catheterization laboratories, whether fixed or mobile. Mobile units may, however, perform therapeutic procedures provided the mobile unit is located on a hospital campus and the hospital has on-site open heart surgery. In addition, hospitals approved to perform therapeutic cardiac catheterizations without on-site open heart surgery backup may temporarily perform these procedures in a mobile laboratory on the hospital's campus during construction impacting the fixed laboratories.

16. **Minimum Physician Requirements to Initiate a New Service:** The initiation of a new therapeutic cardiac catheterization program should require at least two cardiologists with at least one cardiologist having performed an average of 75 therapeutic procedures over the most recent five year period. All participating cardiologists in the proposed program should be board certified or board eligible in cardiology and any relevant cardiac subspecialties.

The applicant agrees to comply by recruiting only cardiologists who meets the criteria.

17. **Staff and Service Availability:** Ideally, therapeutic services should be available on an emergency basis 24 hours per day, 7 days per week through a staff call schedule (24/7 emergency coverage). In addition, all laboratory staff should be available within 30 minutes of the activation of the laboratory. If the applicant will not be able to immediately provide 24/7 emergency coverage, the applicant should present a plan for reaching 24/7 emergency coverage within three years of initiating the service or present a signed transfer agreement with another facility capable of treating transferred patients in a cardiac catheterization laboratory on a 24/7 basis within 90 minutes of the patient's arrival at the originating emergency department.

The applicant complies with this criterion.

18. **Expansion of Services to Include Therapeutic Cardiac Catheterization:** An applicant proposing the establishment of therapeutic cardiac catheterization services, who is already an existing provider of diagnostic catheterization services, should demonstrate that its diagnostic cardiac catheterization unit has been utilized for an average minimum of 300 cases per year for the two most recent years as reflected in the data supplied to and/or verified by the Department of Health.

The applicant complies with this criterion.

The above criterion was use by the Tennessee Department of Health, Division of Policy, Planning, and Assessment staff to calculate the need for Therapeutic Catheterization in the projected service area.

Therapeutic Catheterization in the projected service area

Data Sources: TDH Hospital Discharge Data System (HDDS)

Data Years: 2010-2012 (most recent years of finalized HDDS data)

Methodology: Determine the three year Cardiac Cath weighted volume (diagnostic and therapeutic) performed by each Tennessee hospital in the service area by 13 age groups calculating a single year average. Include all patients seen, both Tennessee resident and non-resident. Include all occurrences of Cardiac Cath ICD-9 Procedure Codes or CPT HCPCS codes. Additional criteria, select only claims with Revenue Code 0481, Cardiology - Cardiac Cath Lab. Summarize cases based on the highest weighted code.

Cardiac Cath ICD-9 and CPT codes and categorizations determined by the Bureau of TennCare and Tennessee Hospital Association.

Note: there was a major shift in CPT coding beginning in 2011. CPT codes from 2010 that were deleted beginning in 2011 were included for that year only.

The service area for the current application includes Crockett, Dyer, Gibson, Lake, Lauderdale and Obion counties. Hospitals found in this area (during the years 2010-2012) are Dyersburg Regional Medical Center, Milan General Hospital, Gibson General Hospital, Humboldt General Hospital, Lauderdale Community Hospital and Baptist Memorial Hospital-Union City.

Note: Milan General Hospital, Gibson General Hospital, Humboldt General Hospital, and Lauderdale Community Hospital did not record any claims with Revenue Code 0481, Cardiology - Cardiac Cath Lab.

Gibson General Hospital and Humboldt General Hospital each closed in December 2013.

Per Joint Annual Reports (JAR) of Hospitals in 2012 there are only two Cardiac Cath labs in operation in the service area:

Dyersburg Regional Medical Center – 1 lab

Baptist Memorial Hospital-Union City – 1 lab

Dyersburg Regional Medical Center

Highest Weighted* Cardiac Cath Services Provided - Hospital Discharge Recorded Data - 2010-2012

Diagnostic Cardiac Caths				
Age Grp	Diagnostic Total	Service Categories		
		CC	PV	EP
Total	761.0	755.0	6.0	0.0
0 - 17	0.0	0.0	0.0	0.0
18 - 29	12.0	12.0	0.0	0.0
30 - 39	72.5	71.0	1.5	0.0
40 - 44	71.0	71.0	0.0	0.0
45 - 49	108.5	107.0	1.5	0.0
50 - 54	89.5	88.0	1.5	0.0
55 - 59	95.0	95.0	0.0	0.0
60 - 64	107.0	107.0	0.0	0.0
65 - 69	72.0	72.0	0.0	0.0
70 - 74	55.0	55.0	0.0	0.0
75 - 79	37.5	36.0	1.5	0.0
80 - 84	28.0	28.0	0.0	0.0
85 +	13.0	13.0	0.0	0.0

Therapeutic Cardiac Caths				
Age Grp	Therapeutic Total	Service Categories		
		CC	PV	EP
Total	31.0	2.0	21.0	8.0
0 - 17	0.0	0.0	0.0	0.0
18 - 29	0.0	0.0	0.0	0.0
30 - 39	3.0	0.0	3.0	0.0
40 - 44	0.0	0.0	0.0	0.0
45 - 49	0.0	0.0	0.0	0.0
50 - 54	3.0	0.0	3.0	0.0
55 - 59	3.0	0.0	3.0	0.0
60 - 64	9.0	2.0	3.0	4.0
65 - 69	6.0	0.0	6.0	0.0
70 - 74	0.0	0.0	0.0	0.0
75 - 79	7.0	0.0	3.0	4.0
80 - 84	0.0	0.0	0.0	0.0
85 +	0.0	0.0	0.0	0.0

CC - Cardiac Catheterization

PV - Peripheral Vascular Catheterization

EP - Electrophysiological Studies

* Cardiac Cath ICD-9, CPT codes and service categories provided by the Bureau of TennCare and the Tennessee Hospital Association.

Note, there was a major shift in CPT coding beginning in 2011.

Source: Tennessee Department of Health, Division of Policy, Planning and Assessment, Office of Health Statistics.

Hospital Discharge Data System, 2010-2012. Nashville, TN.

Baptist Memorial Hospital - Union City

Highest Weighted* Cardiac Cath Services Provided - Hospital Discharge Recorded Data - 2010-2012

Diagnostic Cardiac Caths				
Age Grp	Diagnostic Total	Service Categories		
		CC	PV	EP
Total	85.0	85.0	0.0	0.0
0 - 17	0.0	0.0	0.0	0.0
18 - 29	0.0	0.0	0.0	0.0
30 - 39	1.0	1.0	0.0	0.0
40 - 44	7.0	7.0	0.0	0.0
45 - 49	14.0	14.0	0.0	0.0
50 - 54	8.0	8.0	0.0	0.0
55 - 59	9.0	9.0	0.0	0.0
60 - 64	16.0	16.0	0.0	0.0
65 - 69	9.0	9.0	0.0	0.0
70 - 74	9.0	9.0	0.0	0.0
75 - 79	8.0	8.0	0.0	0.0
80 - 84	4.0	4.0	0.0	0.0
85 +	0.0	0.0	0.0	0.0

Therapeutic Cardiac Caths				
Age Grp	Therapeutic Total	Service Categories		
		CC	PV	EP
Total	0.0	0.0	0.0	0.0
0 - 17	0.0	0.0	0.0	0.0
18 - 29	0.0	0.0	0.0	0.0
30 - 39	0.0	0.0	0.0	0.0
40 - 44	0.0	0.0	0.0	0.0
45 - 49	0.0	0.0	0.0	0.0
50 - 54	0.0	0.0	0.0	0.0
55 - 59	0.0	0.0	0.0	0.0
60 - 64	0.0	0.0	0.0	0.0
65 - 69	0.0	0.0	0.0	0.0
70 - 74	0.0	0.0	0.0	0.0
75 - 79	0.0	0.0	0.0	0.0
80 - 84	0.0	0.0	0.0	0.0
85 +	0.0	0.0	0.0	0.0

CC - Cardiac Catheterization PV - Peripheral Vascular Catheterization EP - Electrophysiological Studies

* Cardiac Cath ICD-9, CPT codes and service categories provided by the Bureau of TennCare and the Tennessee Hospital Association. Note, there was a major shift in CPT coding beginning in 2011.

Source: Tennessee Department of Health, Division of Policy, Planning and Assessment, Office of Health Statistics. Hospital Discharge Data System, 2010-2012. Nashville, TN.

Service Area Hospital	Diagnostic Cardiac Caths	Therapeutic Cardiac Caths	Total Cardiac Caths
Dyersburg Regional Medical Center	761	31	792
Baptist Memorial Hospital - Union City	85	0	85
Totals	846	31	877
# of Cardiac Cath Labs in Service Area (JAR)	2		
Capacity per Lab (defined by standards)	2000		
Total Capacity in Service Area	4000		
Percent of Existing Services to Capacity	21.9%		



JUN 14 PM 12:52
FOR YOUTH DEVELOPMENT
FOR HEALTHY LIVING
FOR SOCIAL RESPONSIBILITY

Melanie M. Hill
Executive Director
Tennessee Health Services and Development Agency
Andrew Jackson Building, Ninth Floor
502 Deaderick Street
Nashville, TN 37243
Re: Dyersburg Regional Medical Center - CN1403-007

Dear Ms. Hill:

I am the CEO of the YMCA of Dyer County. Our Mission is, "*To put Christian principles into practice through programs that help healthy spirit, mind and body for all.*" In fulfilling this mission it is critical that we work with our local hospital to create and sustain programs that promote healthy living for members of our community.

I am writing this letter to request the Agency strongly consider approving this application. It is a shame that members of our community are required to go to Jackson or Memphis to receive advanced cardiac care. I am confident that not only is the hospital fully capable of building this new service, but also that the local and regional patients will support it. I also want the peace of mind of knowing that if my family, friends, or even myself were to suffer a heart attack, we would be able to receive care in Dyersburg and not waste precious time being transferred several miles away.

Last August my father was admitted to Dyersburg Regional Medical Center with chest pains and suffered two heart attacks while being evaluated. The staff on duty did all they could do at the time and revived him twice so they could transfer him to Jackson. Jackson Regional Hospital performed two different procedures trying to save him. Nine hours after his first heart attack he passed away due to heart failure. We lost valuable time stabilizing him for travel almost four hours moving him to Jackson. If we had this opportunity at the Dyersburg Regional Medical Center we might have been able to save him from his death. Please allow our Medical Center the ability to provide advanced cardiac care to serve our community especially when every minute could mean the difference in life or death.

Sincerely,

Randy Butler
CEO of YMCA of Dyer County
P.O. Box 1502
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phone: 731-286-9622
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